Report on FDA Activities Related to Cell Phones and Radiofrequency Radiation

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FDA's Misrepresentations of the FDA's Scientific Research Review and Safety Determinations Regarding Cell Phone and Wireless Radiation Safety

Introduction

This Declaration is submitted by Theodora Scarato, one of the world's preeminent research and educational organizations on health effects of Radio Frequency Radiation (RFR)/Electromagnetic Fields (RFR/EMF). This Declaration documents in detail a broad range of contradictory statements, critical omissions, half truths, haphazard activities and misrepresentations asserted by the FDA over many years regarding the agency's official policy and scientific activities concerning RFR/EMF safety.

The result of FDA's contradictory presentations is the propagation of the false illusion that *safety is assured* for 5G, cell phones and cell towers. Although the FDA asserts it has reviewed "the totality" of the science, it has never completed a hazard or risk assessment of the full body of science. In fact, the FDA has only released a literature review limited in scope to cancer and cell phones. The FDA has not shown a science based evaluation of U.S. human wireless exposure limits, nor of 5G technology, nor of cell tower radiation, nor of impacts to children nor of non cancer health effects such as brain damage and sperm damage, *yet the FDA misleadingly asserts that US exposure limits protect the public.*

Unless the FDA has completed reports and scientific evaluations that have never been made public, the FDA has repeatedly misrepresented its activities in regards to 5G, cell phone and wireless radiation safety limits. As documented in this declaration, when scientists and policymakers request specific information to gain clarity on FDA's policies and it's level of scientific review, the FDA repeatedly refuses to answer questions.

Most detrimentally, the FDA's contradictory presentations have taken on a life of its own. Each misleading or half truth once allowed or encouraged, is quoted, augmented and expanded into a cascade of false safety assumptions, innuendoes, and falsehoods amplified by the media, wireless companies and even elected officials.

Due to the cascade of misinformation the FDA's statements foster, most people believe the following **false narrative**:

> ***FALSE: The FDA has a scientific review process in place whereby FDA scientists have thoroughly reviewed all of the latest science, including 5G infrastructure, and used science based best practice methods to ensure current FCC RFR safety limits are safe for the public.***
>
> ***FALSE: The National Institutes of Health National Toxicology Program studies that found cancer in rats have absolutely no relevance to human health.***
>
> ***FALSE: The FDA's science based determination is that cell phones have such a large 50-times safety factor that they can be used snug to the brain and body, even by children and pregnant women, without any risk whatsoever.***

This Declaration provides copious evidence documenting how the above wireless safety narrative is false.

As we detail in this report, even members of Congress believe that the FDA is ensuring safety for the public, especially when it comes to 5G networks as the FDA website contains verbiage regarding 5G safety. However, when pressed with a question by Theodora Scarato, the FDA replied in an email, "Please be aware the Food and Drug Administration (FDA) does not have regulatory authority over cell phone towers and has not done an assessment on the safety of radiofrequency energy being emitted from antennas located on cell phone towers."

The multitude of hazards to the American public resulting from the FDA's actions and inactions is profound, alarming, continuing, and imminent. Elected officials inaccurately believe that the FDA is ensuring safety against all harms and that they are regularly monitoring the science. As documented in this declaration, FDA's statements to the FCC and Congress that the FDA has evaluated the adequacy of US FCC limits have resulted in major policy and legal decisions at the federal, state and local level which allow significantly increased public exposure to RFR/EMF. When members of the public raise the issue of health effects for children in schools or request accommodations to protect their health they are sent a dazzling array of responses all eventually pointing to the FCC RFR limits that rest on the FDA's unsubstantiated safety assurances.

Yet, the havoc is easily and immediately corrected. All the FDA needs to do is to clarify its official activity, level of reviews and policy on RFR/EMF safety, thus putting a stop to all the misinformation and the resulting confusion.

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On Jan 20, 2022, at 5:23 AM, CDER DRUG INFO <DRUGINFO@fda.hhs.gov> wrote:

Thank you for writing the FDA. Your e-mails was forwarded to the Division of Drug Information in the FDA's Center for Drug Evaluation and Research.

FDA does not regulate 5G technology.

There is information on 5G on the FCC website at: https://www.fcc.gov/5g-faqs

The FCC is pursuing a comprehensive strategy to facilitate U.S. 5G deployment. This strategy includes three key components: pushing more spectrum into the marketplace; updating infrastructure policy; and modernizing outdated regulations. For more information, see the FCC web page: America's 5G Future.

Best regards,
BR
Pharmacist
Division of Drug Information | Center for Drug Evaluation and Research
Food and Drug Administration
Tel: 866-405-5367 or 301-796-6707

In follow-up to our initial conversation, FDA is responsible for protecting the public health from hazardous or unnecessary radiation from radiation emitting *electronic products.* The Federal Communication Commission (FCC) has jurisdiction over all radiofrequency transmitting structures in the United States. Therefore, the 5G tower you inquired about is under the authority of the FCC, not the FDA. I have copied Howard Griboff on this message so that he is aware of the limitation of FDA's authority.

When I inquired into your concerns I found that a few months ago the Deputy Director of FDA's Center for Devices and Radiological Health (CDRH) explained the scope of FDA's regulatory authority as well as responded to your questions. In addition, the Ombudsman for CDRH offered to be your contact if you had any new questions that had not been answered by the Center.

I understand that this issue is very important to you. I hope this information is helpful.

Laurie

Laurie Lenkel
FDA Ombudsman
https://www.fda.gov/about-fda/office-chief-scientist/fda-ombudsman

Executive Summary

The FDA has made numerous misleading misrepresentations and critical omissions regarding the FDA's level of review and risk assessment for the public health risks of 5G, cell phone and wireless radiofrequency radiation (RFR). The American public, elected officials and agencies at the local, state, local and federal level have detrimentally relied on the FDA, erroneously believing that the agency has evaluated the totality of the science, and that the FDA has officially determined that there is no public health risk from exposure.

The FDA's numerous misrepresentations and critical omissions regarding it's activities and level of review of the science convey the false illusion that *safety is assured*.

As detailed in this Declaration, the FDA has not systematically reviewed the "totality" of the evidence to determine public health risks, nor has it evaluated the FCC limits with a science based methodology. The agency has repeatedly refused to answer questions related to its activities regarding wireless radiation, and refuses to correct inaccurate information on its website.

The FDA has omitted that the Agency has no authority in regards to cell tower emissions and has not scientifically evaluated cell tower antenna maximum permissible RFR levels, nor 5G modulations and has not publicly shown any systematic evaluation of published studies on brain development and reproduction. The FDA omits that it has no authority or expertise regarding impacts to non humans- wildlife trees and plants. The FDA is aware that cell phone radiation exposures can be so high that they may exceed the FCC's limits when phones are resting on the body or carried in a pants pocket or bra, but omits this information from its public communications.The FDA is also aware that a child's developing brain and a fetus are more sensitive to cell phone radiation, but has chosen to omit information on children and fetus vulnerability, dangerously downplaying the human health risks to the American public.

The FDA's misleading information has influenced the public, media, medical professionals, courts and government officials at local, state and federal levels which has led to the unchecked rapid proliferation of wireless networks across the nation in schools, neighborhood streets and workplaces.

At the core of the problem is the fact that the FCC's human exposure regulations for wireless RFR/EMF radiation have remained unchanged since 1996, and this is directly due to years of FDA's haphazard activities and silence regarding the health effects of cell phone radiation. As the EPA was defunded from research on RFR/EMF in 1996, the FDA has long been the only federal health agency considered to have authority to opine on RFR/EMF health issues, due to the FDA's power to regulate radiation emitting electronic products under the provisions of the Food, Drug and Cosmetic Act.

In 2013, the FCC opened up an inquiry seeking comment on the adequacy of these 1996 human exposure limits, and the FDA did not respond for years. Then, on April 24, 2019, FDA

Director of the Center for Devices and Radiological Health Dr. Jeffrey Shuren submitted a letter to the FCC with one paragraph dedicated to the issue which stated, *"the available scientific evidence to date does not support adverse health effects in humans due to exposures at or under the current limits…"* Soon after on December 4, 2019 the FCC made a decision **not** to update its 1996 RFR/EMF limits **largely based on this FDA letter,** and the FDA's web pages and FDA Shuren's statements rejecting the conclusions of the National Toxicology Program study that found cancer and DNA damage in rodents.

Environmental Health Trust and 13 petitioners, including Theodora Scarato, filed a lawsuit[1] against the FCC for this 2019 refusal to update the federal regulations, and we argued that the FDA had not shown any substantive science based report nor risk analysis to substantiate their online statements and April 2019 Submission to the FCC.

On August 13, 2021, the United States Court of Appeals for the District of Columbia Circuit made a judgment in our case and ruled that the **FCC had failed to show** that its re-affirmation of those 25-year-old wireless radiation limits was based on a reasoned evaluation of the relevant scientific evidence because it ignored record evidence about children's vulnerability, non-cancer effects, impacts to wildlife and the environment, and the effects of long-term exposures. Importantly, the Court found that the FCC had improperly relied on FDA's "conclusory statements" regarding RFR and health - **the very same statements we document in this Declaration as misrepresentations[2].** The court stated the FDA's statements *"represent a failure by the FDA to address the implication of Petitioners' studies: The factual premise—the non-existence of non-thermal biological effects—underlying the current RF guidelines may no longer be accurate."*

The FDA's subsequent 2020 release of "Review of Published Literature between 2008 and 2018" further proved that the FDA's conclusion of no harm is unsubstantiated by FDA review, because the FDA's literature review was limited to cancer and cell phones only. It did not include a review of the literature on non-cancer health effects (brain damage, oxidative stress, reproductive harm, etc.), and did not include a review of cell tower studies or environmental effects. Importantly, the FDA's 2020 literature review was not a risk assessment nor hazard identification report and it had numerous inaccuracies - inaccuracies which remain uncorrected to this day. **Yet the FDA misleadingly presents this review as proof of safety.**

The FDA's failure to honestly present its EMF activities, and its misrepresentations regarding the adequacy of the FCC's human exposure limits, have led to a rapidly increasing nationwide RFR/EMF exposure for all age groups, putting the entire U.S. population at risk. The FCC's limits and the FDA's misrepresentations are used as proof of safety for the rapid deployment of 4G and 5G wireless networks nationwide. Because of this failure, government officials at all levels have rejected evidence presented to them by constituents indicating that densified

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[1] Full Opening Brief of EHT et al v FCC 8/14/2020 ORAL ARGUMENT REQUESTED 20-1025 (Lead); 20-1138 (Consolidated) UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

[2] The FCC cited three statements by the FDA as substantiating their determination: a 2/2018 FDA statement (saying the "totality" of the research shows no harm, a 4/2019 FDA letter (with one paragraph discounting the relevance of the NTP results), and the 12/4/2019 dated FDA website page "Do cell phones pose a health hazard?" (which does not reference the FDA research review).

wireless infrastructure is unsafe, and instead officials are funding new wireless projects in schools and communities. Half the states in the country have passed small cell legislation which strip local authority and fast-track cell tower installations into neighborhoods, many allowing cell antennas less than 50 feet from homes and bedrooms, significantly increasing the environmental RFR/EMF exposures and leading to documented harms.

People have been injured, and will continue to be injured, by wireless networks and wireless devices brought to market under the FCC's 25-year-old, outdated regulations — rules that the FDA has rubber stamped by its inaction, omissions and misrepresentations.

The FDA omits critical information about its scope of authority and level of review to policymakers, allowing false safety assumptions to be widely disseminated. For example, when asked about the safety of 5G networks, the FDA omits to members of Congress that it has no authority regarding cell tower antenna radiation, and the FDA also omits that no US environmental agency is actively monitoring the escalating environmental RFR/EMF exposures for any adverse effects to wildlife[3]. The FDA omits that it has not systematically reviewed the implications of another type of non ionizing EMF from electronic devices - magnetic field Extremely Low Frequency radiation exposure from cell phones and wireless devices used in body contact positions. The FDA omits that the Interagency RFR workgroup is defunct, and that its advisory committee on the issue has not met since 2016.

Unless the FDA is withholding its science-based reports from the public, all of the publicly available evidence indicates that the FDA is misrepresenting its EMF activities and level of review on the issue, creating false safety assurances. It is certainly possible that the FDA has performed a robust systematic scientific review and risk assessment which has not been made public. If so, the FDA has failed to be transparent to the public and to federal agencies and elected representatives who have repeatedly requested such information. If indeed a robust systematic science based FDA risk assessment exists, it should be made public and subject to scrutiny. Until the FDA publicly releases such documentation, we believe that the FDA is misrepresenting this issue in numerous areas as details in this Declaration.

In short, the American people believe that their government is watching out for them. They believe that the FDA - the U.S. health agency with authority in regards to wireless radiation - is doing its job. This Declaration provides proof that this is not the case.

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[3] Research has documented numerous environmental effects from RFR exposure including tree damage, biochemical changes in plants and harm to pollinators and wildlife.
Waldmann-Selsam, Cornelia, et al. "Radiofrequency Radiation Injures Trees around Mobile Phone Base Stations." *The Science of the Total Environment*, vol. 572, Dec. 2016, pp. 554–69. *PubMed*.
Halgamuge, Malka N. "Review: Weak Radiofrequency Radiation Exposure from Mobile Phone Radiation on Plants." *Electromagnetic Biology and Medicine*, vol. 36, no. 2, 2017, pp. 213–35. *PubMed*.
Balmori, Alfonso. "Electromagnetic Radiation as an Emerging Driver Factor for the Decline of Insects." *Science of The Total Environment*, vol. 767, May 2021, p. 144913. *ScienceDirect*.
Levitt, B. Blake, et al. "Effects of Non-Ionizing Electromagnetic Fields on Flora and Fauna, Part 3. Exposure Standards, Public Policy, Laws, and Future Directions." *Reviews on Environmental Health*, Sept. 2021. *PubMed*.

As the legacy of asbestos, lead, and cigarettes inform us, the FDA's failure to fully assess and mitigate risk will lead to irreversible harms for generations to come.

Years of Misrepresentations and Haphazard Activities

To substantiate the long history of misrepresentations by FDA staff, Scarato has compiled years of personal direct email communications with FDA staff initiated by an in-person meeting between Devra Davis, PhD and Theodora Scarato at FDA headquarters on September 23, 2014. In that meeting, Davis and Scarato presented research linking RFR to cancer and reproductive damage, as well as case reports of young women developing unusual breast cancers directly underneath where they stored a transmitting cell phone in their bra. The FDA should inform the public that cell phones should not be in a pocket or bra, as FCC regulatory limits would be violated.

The subsequent email conversations over the years between Scarato and FDA staff showcase a haphazard approach by the agency, a refusal to warn the public about clear violations of FCC exposure limits, and a disregard for credible science clearly indicating harm, especially for children. The FDA clearly stated they had not performed a research review in a 2016 email and refused to answer the question of whether the FDA had reviewed the FCC limits. When the NTP released its findings in 2016 and 2018, Scarato repeatedly requested the FDA update it's website as it linked to 2010 information, but the FDA never did, at least until the February 2020 rewrite. FDA Importantly, when repeatedly asked what specific levels of RFR exposure would trigger FDA's action on the issue, and when asked to correct inaccuracies, FDA staff repeatedly refused to answer, exemplifying the haphazard activities and lack of transparency and misrepresentation.

As additional evidence for this Declaration, Scarato has collected and analyzed FDA's letters to members of Congress, to state/local officials, and to scientists. Furthermore, included in this document are statements by the FCC referencing the FDA's false safety assurances, and dismissing the National Toxicology Program study which found adverse effects in animals. The FDA's misleading website information on cell phone radiation, and the FDA's Dr. Shuren's online statements, also provide critical evidence of the FDA's misrepresentations to the public. We also have provided a short list of examples of how the wireless industry then uses the FDA verbiage to amplify the false message that safety is assured.This information is listed in Section X. Appendix of Evidence of FDA Misrepresentations and influence on Congress, State Agencies and the Media

The FDA Downplays the Significance of the National Toxicology Program Study Which Proves Non Thermal Effects, and Refuses to Correct the Inaccurate FDA Information on The Study

FDA's Dr. Jeffrey Shuren has repeatedly stated that the FDA does not agree with the NTP study's cancer determinations, has publicized this disagreement on the FDA website, and also

in one paragraph of his April 2019 letter submitted to the FCC regarding FCC's human exposure limits. The FDA's rejection of the NTP study for being an "animal" study that the FDA itself nominated, displays a shockingly two-faced and hypocritical attitude to animal testing. Because every agent known to cause cancer in humans also produces cancer in animals when adequately studied, animal studies have constituted a bedrock of FDA operations for drug development and toxicology evaluation since the agency's inception.

Determinations based on animal studies from the 1970s and 1980s remain the sole criterion on which cell phone testing protocols have rested as documented in ANSI/IEEE C95.1-1991. Yet, when findings from state-of-the-art National Toxicology program animal studies document the damaging cumulative chronic impacts of non-thermal levels of RFR/EMF, the FDA staff rejects the study as not relevant to humans. Numerous scientists have determined that the NTP's large scale animal studies, paired with the Ramazzini Institute research and published human studies that have found an association between cell phone use and cancer, indicate that RFR/EMF now meets criteria to be a human carcinogen.[4,5,6] Children's developing brains are more sensitive to RFR radiation and their unique physiology results in their absorption of proportionately more RFR compared to adults.[7]

Instead of rejecting the NTP study, many scientists argue the FDA needs to fulfill the intent of their nomination of the study to the NTP, and conduct a quantitative risk assessment from the NTP data so that the FCC can develop health-protective exposure standards. However, the FDA has not responded to the scientists who have repeatedly written to the agency regarding a quantitative risk assessment. Nor has the FDA responded to these expert scientists' requests to correct the FDA's inaccurate statements regarding the NTP and to be transparent about what experts were involved in the literature review that downplays the NTP study.

FDA's Misrepresentations Regarding Their Level of Scientific Review for Cell Phone and Radiofrequency Radiation.

In this Declaration we break down the FDA's misrepresentations one by one. For each misrepresentation, we document the facts confirming that the FDA's representation is erroneous and misleading. To be clear, in this Declaration we are not making scientific arguments as to whether RFR is harmful or not, but instead we are addressing the FDA's critical omissions and lack of honesty and transparency in its statements regarding health effects from RFR/EMF. We then follow with documentation of the far-reaching deleterious impact of these misrepresentations to public health and the environment.

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[4] Coureau, Gaëlle, et al. "Mobile Phone Use and Brain Tumours in the CERENAT Case-Control Study." *Occupational and Environmental Medicine*, vol. 71, no. 7, July 2014, pp. 514–22. *PubMed*.
[5] Hardell, Lennart, and Michael Carlberg. "Mobile Phone and Cordless Phone Use and the Risk for Glioma - Analysis of Pooled Case-Control Studies in Sweden, 1997-2003 and 2007-2009." *Pathophysiology: The Official Journal of the International Society for Pathophysiology*, vol. 22, no. 1, Mar. 2015, pp. 1–13. *PubMed*.
[6] Hardell, Lennart, et al. "Use of Mobile Phones and Cordless Phones Is Associated with Increased Risk for Glioma and Acoustic Neuroma." *Pathophysiology: The Official Journal of the International Society for Pathophysiology*, vol. 20, no. 2, Apr. 2013, pp. 85–110. *PubMed*.
[7] Fernández, C., et al. "Absorption of Wireless Radiation in the Child versus Adult Brain and Eye from Cell Phone Conversation or Virtual Reality." *Environmental Research*, vol. 167, Nov. 2018, pp. 694–99. *ScienceDirect*.

Below is a short summary of the misrepresentations and the documentation. For the comprehensive documentation please go to the corresponding section for each misrepresentation in the body of the Declaration.

Misrepresentation #1: The FDA evaluated the "totality" of scientific data to make a determination that there are no health effects from cell phones and that FCC radio frequency radiation (RFR) limits do not need to be changed.

Fact: The FDA has not publicly released any reports or systematic reviews that show the FDA has reviewed all health effects. The one report the FDA did release in 2020 is simply a literature review filled with inaccurate statements the FDA refuses to correct, despite numerous letters by experts including longtime NIH scientists. Importantly, the 2020 literature review is not a systematic review, nor is it a hazard or risk assessment.

The FDA does not inform members of Congress that their literature review is limited to only cancer (not memory problems, brain damage, sperm damage, etc.) and cell phones (not Wi-Fi, Bluetooth, 5G small cells, OTARD devices, etc.). The FDA also omits that no federal agency is actively reviewing the science on 5G modulation or cell tower antenna radiation.

The full documentation of how the FDA is misrepresenting that it has evaluated the "totality of the science can be found in Misrepresentation #1.

Misrepresentation #2: The FDA's "Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer" released in 2020 is a scientifically valid risk assessment.

Fact: Although the FDA inaccurately states in its 2020 Literature Review that they "completed an updated radiofrequency (RF) exposure risk analysis," this literature review is not a scientifically defensible "risk analysis" based on the best practice guidelines for risk assessment developed by US scientists. Further, the FDA Literature Review is not a systematic review, nor a review of the adequacy of FCC limits, and it is riddled with major errors that the FDA refuses to correct. However the FDA misrepresents this review as substantiating its conclusions that FCC's limits do not need to be changed, and the review is used on the FDA's web pages to substantiate the Agency's assertion that cell phones are safe. Numerous scientists have called on the FDA to retract this review, but to date have received no response from the FDA.

For the full documentation on the FDA's misrepresentations of its Literature Review please go to Misrepresentation #2.

Misrepresentation #3: The FDA has evaluated the science on specific non-cancer effects such as oxidative stress, impacts to reproduction, and people with electromagnetic sensitivity.

Fact: The FDA has misrepresented that they have adequately reviewed specific non-cancer health endpoints such as oxidative stress and damage to reproduction - but has never publicly released any scientific report documenting that the FDA systematically reviewed these issues. Despite highlighting the issue of electromagnetic sensitivity on their website, the FDA has shown no science based reports nor review of this issue as well. Although the FDA has been sent several studies and published reviews on this issue indicating harmful non-cancer effects, the FDA has taken no action to properly review these issues, nor shared this science with the public.

For the full documentation on the FDA's misrepresentations of its review on non cancer endpoints please go to Misrepresentation #3.

Misrepresentation #4: The FDA states that "the majority of studies" do not show an association between cell phones and health problems.

Fact: The FDA has stated "the majority of studies" do not show an association between cell phones and health problems, even though the FDA has not publicly released any report or research list that looked at all the studies on cell phones and health issues (cancer and non-cancer) in order to make this numerical determination. Furthermore, independent scientific evaluations on several endpoints find that the majority of studies do show adverse effects.

For the full documentation on the FDA's misrepresentations of its determination on the "majority of studies" please go to Misrepresentation #4.

FDA Misrepresentation #5: The FDA states that RFR studies which find biological effects "have not been replicated".

Fact: Biological effects have been replicated. In fact, the FDA's own literature review contains replicated research indicating RFR is a tumor promoter. False sweeping general statements like this one on the FDA's public website only serve to downplay the health issue to the American public and government. While RFR research is complex, and numerous studies do indeed suffer from critical limitations, exposure issues and confounding factors, the fact is that numerous systematic reviews have repeatedly found the same types of biological effects, and there are research studies that have been in fact replicated.

For the full documentation on the FDA's misrepresentations of lack of replication of research showing harm please go to Misrepresentation #5.

Misrepresentation #6: The FDA presents inaccurate information about its own sponsored $30 million U.S. National Toxicology Program (NTP) animal study findings.

Fact: The FDA has presented inaccurate information about the NTP study findings to the public, elected officials and federal agencies. The FDA has not corrected their statements, despite being provided factual information and a science-based request for corrections by NIH scientists and experts. Furthermore, the FDA mischaracterizes the study by omitting the key findings of cancer and DNA damage and putting forward unfounded criticisms.

The end result of this deception is that the public believes this large-scale animal study has no relevance to human health, elected officials believe the study is irrelevant to policy decisions, and the U.S. federal regulations for human RFR/EMF exposure are believed to be adequate to protect public health. The FDA omits that the NTP study is significant because biological effects were found at non-thermal levels, indicating the basis for FCC maximum RFR/EMF exposure limits - that thermal effects are the only important effects - is no longer accurate.

As Dr. Ronald Melnick states, *"The NTP studies were conducted to test the widely-held assumption that cell phone radiofrequency radiation could not cause cancers or other adverse health effects (other than by tissue heating) because this type of radiation (non-ionizing) did not have sufficient energy to break chemical bonds. The NTP findings that cell phone radiation caused cancers in the heart and brain, DNA damage in brain cells, heart muscle disease and reduced birth weights clearly demonstrate that the assumption that non-ionizing radiation cannot cause cancer or other health effects is wrong."*

For the full documentation on the FDA's misrepresentations of the National Toxicology Program study please go to Misrepresentation #6.

Misrepresentation #7: The FDA has evaluated the FCC's human exposure limits for RFR and come to a determination that the limits are protective based on its scientific review of the limits.

Fact: Despite the FDA's misleading statements to several members of Congress, the FDA has never released any science based report that evaluates the FCC's human exposure limits for RFR/EMF and determined with science based methods that FCC limits are adequately protective of all harms. Instead, all the FDA has produced is its 2020 literature review *focused only on cancer and cell phones.* The FDA literature review is not a systematic review, not a hazard or risk assessment, and not a review of FCC limits - whereby levels of exposure in studies would be compared to the FCC RFR/EMF limits. In fact, the FDA literature review does not even reference the actual FCC limits.

For the full documentation on the FDA's misrepresentations regarding its level of evaluation of FCC's human exposure limits please go to Misrepresentation #7.

Misrepresentation #8: The FDA states they "continually monitor the scientific studies" yet the FDA shows no evidence of regular research monitoring nor regular scientific reviews.

Fact: The FDA shows no documented evidence of "regular" research reviews nor "regular" research monitoring. There are no monthly or yearly reports, no research updates and no publicly available notes or agendas from meetings on the issue of RFR. The FDA publicly states that the agency will act if credible science shows harm, but has never defined what it deems as credible, nor the process by which it evaluates or monitors the RFR issue. If the FDA is doing regular monitoring of the science, its process and opinions are being kept a secret from the public. As an example, the FDA website has not been updated since February 2020, despite numerous studies published since that date indicating adverse health effects. The FDA Literature Review was also not updated to include the 2020 genotoxicity paper by the National Institute of Environmental Health Sciences National Toxicology Program scientists (Smith-Roe et al., 2020[8]) nor to include the American Cancer Society funded Yale study that links thyroid cancer to cell phone use in people with a type of common genetic variation (Luo et al., 2020[9]).

For the full documentation on the FDA's misrepresentations regarding its "continuous monitoring of the scientific studies" please go to Misrepresentation #8.

Misrepresentation #9: The FDA states there is "scientific consensus" that RFR radiation is safe and safety is assured.

Fact: The FDA repeatedly and inaccurately states there is "scientific consensus" that cell phones are safe, despite the fact that the FDA is fully aware that hundreds of scientists and thousands of medical doctors are warning that the science indicates serious health effects, and they recommend that the public should reduce its exposure to RFR/EMF. The FDA also states that there is a scientific consensus that cell phones specifically do not cause cancer, despite the fact that numerous authors in numerous published papers conclude RFR/EMF is a carcinogen.

As Dr. Ronald Melnick, now retired from 28 years as an NIH scientist, states in his letter to the FDA:

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[8] Smith-Roe, Stephanie L., et al. "Evaluation of the Genotoxicity of Cell Phone Radiofrequency Radiation in Male and Female Rats and Mice Following Subchronic Exposure." *Environmental and Molecular Mutagenesis*, vol. 61, no. 2, Feb. 2020, pp. 276–90. *PubMed*.

[9] Luo, Jiajun, et al. "Genetic Susceptibility May Modify the Association between Cell Phone Use and Thyroid Cancer: A Population-Based Case-Control Study in Connecticut." *Environmental Research*, vol. 182, Mar. 2020, p. 109013. *ScienceDirect*.

> "The statement on the FDA website that there is a "scientific consensus on cell phone safety" is totally wrong and should be removed since there is no scientific consensus supporting this claim. In contrast, numerous experts in the field have reported evidence that current levels of cell phone radiation can be harmful to human health."

For the full documentation on the FDA's misrepresentations regarding "scientific consensus of safety" please go to Misrepresentation #9.

Misrepresentation #10: The FDA states that children and pregnant women are adequately protected by FCC limits despite no publicly available review on the risks posed to children, pregnant women and the fetus- who are more vulnerable due to their rapidly developing brains and higher absorption of RFR.

Fact: For decades the FDA has repeatedly presented that there is no need for children or pregnant women to reduce RFR/EMF exposure because the FDA has determined that FCC exposure limits are adequately protective. Yet the FDA has shown no evaluation of the research on children's unique vulnerability, nor any evaluation of effects during pregnancy nor any systematic evaluation of how FCC limits have incorporated recent research on children. FDA's 2020 issued Literature Review did not focus on children's vulnerability. In fact, a search of the word "children" in the FDA's literature review finds only three studies that considered children specifically, and no studies reviewed children's deeper RFR/EMF penetration, impacts to a child's developing brain, or to prenatal development.

For the full documentation on the FDA's misrepresentations regarding children and pregnancy please go to Misrepresentation #10.

Misrepresentation #11: The FDA presents to the public that cell phones are safe in body contact positions, well aware that phones in body contact positions exceed the FCC's federal RFR exposure limits.

Fact: The FDA is aware that FCC limits can be exceeded when phones are tested in body contact position and well aware that the public has no idea of this fact. The FDA knowingly allows the American public to be exposed to RFR/EMF levels in excess of the regulatory limit, yet the FDA's website pages have images of smiling people with cell phones against their heads — communicating the message that phones are safe near the body. The FDA website does not have any warnings to the public explaining that all cell phone manufacturers have special instructions — fine print warnings — buried deep in the cell phone manuals that say to keep the phone at a specified distance away from the body: from 5 to 25 millimeters (¼" to 1").

See the fine print warnings here.

The FDA says there is “a large safety margin” that is protective, yet cannot answer our repeated requests to define *how large the safety margin is,* nor at what RFR level past the FCC regulatory limit the FDA would act to enforce the limit or warn the public. The FDA shows no review of recent research to even determine at what level above the FCC limits the FDA would act. The FDA lack of clarity on the threshold of harm it subscribes to has resulted in the current situation where people of all ages carry phones in body contact positions day and night, and pregnant women rest wireless devices on their abdomen, unaware that they could be exposing their fetus to RFR/EMF which violates FCC exposure limits.

For the full documentation on the FDA’s misrepresentations regarding the safety of cell phones in close body proximity please go to Misrepresentation #11.

Misrepresentation #12: The FDA misrepresents the existence of a 50 times safety factor in relation to cell phone radiation exposure limits.

Fact: The FDA misrepresents the existence of a 50 times safety factor by confusing the public, and omitting the complete technical information needed to understand the reality that there is, in fact, no 50 times safety factor for brain tissue exposure when it comes to local SAR limits used in cell phone regulatory premarket tests.

Most of the public, elected officials and scientists (who are not bioelectromagnetic experts) do not understand the complexity of the FCC’s human exposure limits, nor that there are two types of RF SAR limits (as well as Maximum Permissible limits for cell tower emissions). However, the FDA is fully aware of the difference. The reality that there is no 50 times safety factor for the Local SAR Limit for brain tissue is a fact, even among scientists who do not believe that there are health effects from RFR at nonionizing levels. However the FDA strings sentences together so that it seems like there is a 50 times safety factor for cell phone radiation local SAR limits. Again, we have repeatedly requested that the FDA respond to our questions about what the safety margin for cell phone local SAR is, and the FDA has never responded to these questions.

For the full documentation on the FDA’s misrepresentations regarding the non existent 50 times safety margin for cell phones please go to Misrepresentation #12.

Misrepresentation #13: The FDA misrepresents its level of review of 5G technology, communicating that 5G technology is safe.

Fact: FDA's Dr. Shuren sent letters to members of Congress after requests regarding the potential health effects of 5G networks which create the illusion that the FDA has evaluated 5G technology and determined 5G technology is safe. First, the FDA has no authority in regards to RFR emissions from cell tower antennas, and omitted this fact in its response to members of Congress. Further, the FDA has never publicly released any reports focused on 5G modulations, nor systematically reviewed scientific citations specific to 5G technology emissions. As an example, in the FDA's 2020 Literature Review the word "5G" is absent, and none of the studies the FDA reviewed were noted to specifically include 5G modulations.

While it is true that 5G networks will utilize frequencies covered in earlier technology generations (and frequencies considered in the FDA's literature review), many 5G networks will also include higher frequencies, new technologies, and more complex signal characteristics and antenna systems. Furthermore, 5G networks will rely on hundreds of thousands of densified new "small cell" towers that are part of a 5G technosphere that includes **billions** of "smart" wireless devices — all of which will significantly increase ambient environmental RFR/EMF exposures compared to earlier generations of wireless technology. Yet the FDA misrepresents that safety is assured, as it has not shown any review of both the increased daily RFR/EMF exposure, nor the specific impacts of 5G technology modulation on humans and the environment.

For the full documentation on the FDA's misrepresentations regarding their review of 5G technology please go to Misrepresentation #13.

FDAs Critical Omissions

Hand in hand with FDA's misrepresentations are the FDAs critical omissions. Members of Congress and elected officials, government agency staff, the public and media do not understand the complexity of this issue and thus are unaware of the full landscape in regards to EMFs. If they were made aware of the information the FDA omits they would see the lack of accountability at the federal level on this issue. They would understand that the FDA cannot offer a full safety assurance as it does not even have full authority in regards to the issue.

FDA's omissions related to FDA's role and authority in regards to EMFs.

1. FDA has only presented activities in relation to electronic devices such as cell phones- not other wireless devices such as routers, laptops, security systems, Wi-Fi, Bluetooth,

cell towers etc. However, according to the Food, Drug, and Cosmetic Act the FDA could be addressing all consumer electronic devices, not just cell phones. Yet the FDA seems to have chosen to ignore other devices.
2. FDA omits that it has no authority in regards to telecommunications infrastructure such as cell towers, or 5G/4G "small" cell towers and the FDA has done no science based review on health effects from the cumulative emissions of this equipment.
3. FDA omits that it has no authority nor expertise regarding impacts to wildlife or natural environment (i.e trees, plants) and not reviewed adverse effects to flora and fauna.

FDA's omissions related to FDA's level of review regarding EMFs.

1. FDA omits it has not shown review of science on non- cancer effects.
2. FDA omits it has not shown review of science in relation to 5G technology.
3. FDA omits it has not performed a public risk analysis of RFR.
4. FDA omits it has not analyzed the FCC limits in relation to the current body of science.
5. FDA omits that no other federal health and safety agency is actively engaged on this issue.

FDA omits it has not engaged in activities regarding magnetic field EMFs.

1. FDA omits that it has authority to regulate both RFR **and magnetic field EMF emissions** from consumer electronic devices according to the Federal Food, Drug, and Cosmetic Act **refers to "electronic product radiation."** However the FDA seems to have chosen only to address RFR emissions and has shown no activities in relation to the scientific review of health effects from magnetic field EMF.
2. FDA omits that it has not reviewed the science on health effects from magnetic field electromagnetic exposure.
3. FDA omits how the public can reduce exposure to magnetic fields or ELF EMF.

FDA omits extensive information to the public on how and why to reduce EMF exposure.

1. FDA omits that hundreds of scientists are warning that FCC limits are not adequate protective and that the public should reduce exposure. Instead FDA downplays science indicating risk and communicates that reducing exposure is not necessary.
2. FDA omits science indicating children and the fetus are more vulnerable as their rapidly developing brains are more sensitive.
3. FDA omits numerous strategies to reduce cellphone radiation exposure and only presents a short list of 4 ways.
4. FDA omits a robust list of sources of RFR exposure- all the ways that people are exposed from cell towers, to video games, to phones to Wi-Fi printers.

5. FDA omits strategies to reduce exposure from wireless, Bluetooth and Wi-Fi devices such as speakers, gaming consoles, Wi-Fi routers and baby monitors.
6. FDA omits that issuing wired internet and telephone connections eliminates RFR exposure.
7. FDA omits reference to scientific research showing adverse effects from exposure.

FDA omits critical information related to the NTP study findings and FDA's involvement.

1. FDA omits that the findings of an adverse effect at non thermal exposure levels means that the basis for FCC limits is no longer valid.
2. FDA omits the actual findings of the NTP studies- increased brain and heart tumors, DNA damage and heart damage and also omits the conclusion of "clear evidence of cancer" in male rats.
3. FDA omits that it has known the NTP design for years - to test the assumption that heat is the relevant factor- and yet the FDA has never contacted the NTP to communicate that the animal study the FDA asked for was irrelevant to understanding effect to humans.
4. FDA omits that it did not offer comments during the NTP peer review in March 2018.

FDA omits that the advisory and interagency groups thought to be addressing this issue are in fact defunct and have not reviewed the RFR health issues.

1. FDA Omits that the Radiofrequency Interagency Work Group (RFIAWG) is defunct and quietly removed references off its website.
2. FDA omits that the FDA's advisory committee- the Technical Electronic Product Radiation Safety Standards Committee has not reviewed the RFR nor EMF health issues and has not met since 2016 having 9 vacancies.

The numerous implications of these omissions are far reaching. Wireless companies present inaccurate information regarding the RFIWG group communicating a false illusion of safety and a collaboration and oversight that does not exist.

As an example, industry consultant Jerrold Bushberg presented an "Introduction to Potential Health Considerations of 5G Networks" at the Beverly Hills California Health and Safety Commission Meeting on February 24, 2020 and referenced the RFIWG *despite the fact that it is defunct* (See Agenda, Watch video, See full transcript). He presented a slide about the group and stated:

Minute 1:08:20 "Its now 2020, whose taking account of the current science because the NCRP has not been asked to update this report since it was issued and that is the job of the federal interagency agency working group for RF safety surveillance [referring to the RFIWG in a slide at minute 1:08:54]. Their members include individuals from the EPA, FDA NIOSH, OSHA and the FCC and this group meets six times a year, either by person or tele conference. Primarily just to review what is going on around the world and they go to meetings and ask the question whether they think the standards in the US are still reasonable and in-line with what is happening around the world."

CITY OF BEVERLY HILLS
455 NORTH REXFORD DRIVE, BEVERLY HILLS, CA 90210
Federal Interagency Agency Working Group (RF Safety Surveillance)
Environmental Protection Agency: (EPA)
Food and Drug Administrati (FDA)
National Institute of Occupati Health & Safety (NIOSH)
Occupational Health and Safety Administration (OSHA)
Federal Communication Commission (FCC)
This Group meets/teleconference 6 times per year
1:08:53 / 2:31:45
CC
Health and Safety Commission Meeting

As the FDA has also omitted a robust presentation on sources of RF exposure and on how to reduce RFR exposure, the public is fully unaware of the numerous ways to reduce exposure and engage in behaviors that increase their exposure unknowingly.

The full details and documentation on this issue can be found in the section FDA's critical omissions.

The FDAs Lack of Transparency in Regards to Its Activities and Policies

The FDA has repeatedly refused to respond to letter from government entities, members of Congress and scientists who have written with questions directly addressing the FDA's activities and level of review. For example:

- **The New Hampshire State Commission on 5G** wrote to the FDA with several questions, but the FDA responded without directly addressing the questions and instead presented a cursory opinion with just a few paragraphs.
- **Numerous scientists** wrote the FDA in 2020 with questions as well as for a retraction of the FDA literature review. In these letters Dr. Melnick specifically documented the inaccurate information and asked for corrections. The only response was from FDA's Dr. Jeffrey Shuren in a March 24, 2020 letter to Theodora Scarato with one sentence that said *"thank you for sharing your and your colleagues' concerns with. We appreciate your feedback."* The corrections have not been made.
- When the Office of Senator Tammy Baldwin wrote the FDA with specific questions, the FDA responded with a September 8, 2020 letter that ignored the specific questions but instead stated that:

  > *"The FDA published a detailed literature review of all scientific evidence that has become available for over the past decade and updated our webpages related to all aspects of radiofrequency radiation from cellphones* ***[thus misrepresenting the FDA level of review]*** *Based on this extensive risk analysis* ***[again misrepresenting the FDA's level of review],*** *our determination remains consistent that there is no scientific evidence that warrants a change in cell phone safety limits, and that there is insufficient evidence to demonstrate a causal link between cell phones and cancer in the population. We believe that all of the questions contained in your constituent's letter are answered in the publicly available information* ***[although this is not the case as the questions to the FDA in that letter are not answered on the website at all],*** *and I have included links below to the relevant information."*

- **Theodora Scarato has repeatedly written to the FDA** asking for answers to follow up questions from her years of email communications and the FDA states they will no longer respond.
  See the questions here in Scarato email communications to the FDA .

Examples of questions that remain unanswered by the FDA include:

- In light of the French government tests showing excess radiation from phones at body contact, what steps is the FDA taking to address the fact that cell phones and wireless devices have RFR levels that exceed FCC limits when devices are placed at body contact?
- What FDA scientific review substantiates the FDAs statement concerning the safety factor?
- Why is the FDA ignoring the fact that the NTP exposure levels were comparable to FCC's localized public SAR limits and all of them were within occupational localized SAR limits.

- We would like to know why the FDA has not taken action to inform the public about the separation distances that cell phones should be from the body in light of published analysis[10].
- Does the FDA have a specific SAR level that will trigger a FDA action?
- Will there be any premarket safety testing for 5G technology by the FDA to understand the long term effect on human health?
- When did the FDA do a systematic review of the scientific evidence to evaluate impacts on human health?
- The DNA and tumor findings of the NTP indicate non thermal effects from long term exposure as the animals were exposed at levels considered "non thermal. " What is the process by which the FDA is going to integrate this information regarding non thermal exposures into an opinion of the safety of exposure limits for RFR both occupational and for the public ?

The Nationwide Impact of the FDA's Misrepresentations, Omissions and Lack of Transparency is Serious and Deleterious

The FDA's lack of clear policy has led to a cascade of policy decisions and court rulings that put the public in harm's way. Representative Anna Eshoo and Senator Jeff Merkley described the far reaching impact of FDA's information in their letter to the FDA requesting the FDA's science review of 5G and wireless networks that:

> *"While FDA does not have premarket review authorities for cell phones, its information is used by the Federal Communications Commission to set the standards for exposure limits of radiation from cell phones, which cell phone manufacturers must follow. Second, the public relies on conclusions published on FDA's website. Third, scientists and researchers use this information to assess methodologies and to inform their own own research questions"*

Elected officials, the military and agencies at the local, state and federal level are being influenced by the FDA's information and making policy decisions on the myths created by the FDA misinformation.

Below are a few examples for federal, state, local, media, medical and public implications. Extensive documentation on each of these issues can be found in the section "The Nationwide Impact of the FDA's Misrepresentations, Omissions and Lack of Transparency is Serious and Deleterious"

[10] Gandhi, Om P. "Microwave Emissions From Cell Phones Exceed Safety Limits in Europe and the US When Touching the Body." *IEEE Access*, vol. 7, 2019, pp. 47050–52. *IEEE Xplore*.

Federal Policy: The fact that the FDA misrepresented its level of scientific review and risk assessment regarding the science on non-cancer health effects to the FCC led to the FCC's 2019 refusal to update FCC's 1996 human exposure limits. The FCC used the FDA's website, public statements and the FDA's April 24, 2019 letter (that has one paragraph on RFR limits) to support the FCC's 2019 determination (after a six-year inquiry) that the FCC's 1996 human exposure limits for RFR did not need to be changed.

Despite the fact that FCC's RFR limits are based on the assumption that heating is the only harm and do not protect against biological effects and despite the fact that the $30M National Toxicology Program (NTP) study confirmed in a highly controlled study that RFR can cause cancer and DNA damage at non heating levels challenging the basis for the FCC's 1996 limits- the FDA entirely dismissed the study and downplayed the results to the FCC, the American public and Congressional officials. In turn the FCC affirmed its 1996 limits in 2019.

The FCC's human exposure limits are relied upon by every level of government as proof of safety. This is why the FDA's misrepresentations must be urgently addressed.

Although the August 13, 2021, the United States Court of Appeals for the District of Columbia Circuit judgement found the FCC's reliance on the FDA's information as "arbitrary and capricious," it is possible that the FDA could decide to *again misrepresent the science to the FCC* as it previously did regarding the NTP study and cancer. The FDA must clarify its policy in regards to RFR to ensure the FCC has complete information in its upcoming response to the court mandate.

Lack of Oversight: FDA's misrepresentations have resulted in a lack of appropriate oversight in Congress. The Congressional Committees tasked to provide oversight aren't even aware this issue is in need of oversight. Notably Senator Tammy Baldwin, Senator Feinstein and Senator Merkley are all members of the U.S. Senate Committee on Appropriations Subcommittee Agriculture, Rural Development, Food and Drug Administration, and Related Agencies that have oversight of the FDA and all have written letters void of action to ensure accountability on the issue.

An example of how elected officials inaccurately believe there is oversight and accountability on the issue showcase in U S. Representative Scott Fitzgerald November 5, 2021 letter which erroneously states that, *"In addition to the FCC, Federal health and safety agencies such as the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) have been actively involved in monitoring and investigating issues related to radio frequency (RF) exposure."*

Congress Repeating FDAs Misrepresentations: In fact, members of U.S Congress are so misled, that they are communicating erroneous information to their constituents related to the FDA's level of review as detailed in this Declaration in the section "Influence to Congress."

An example of how the FDA's misinformation has propagated false illusions of safety leading to members of Congress asserting nonfactual statements based on the FDA's misinformation is illustrated by the case of Representative Anna Eshoo and Senator Jeff Merkley's communications with the FDA.

- On July 18, 2019, Representatives Anna Eshoo and Senator Jeff Merkley wrote a letter[11] to the FDA asking the agency details about the scientific review the FDA purportedly did to determine 5G and wireless radiation was safe and that RFR limits were protective.
- On September 9, 2019 the FDA responded with a letter[12] filled with misrepresentations and critical omissions - as discussed in this Declaration - which created the impression that the FDA had reviewed the full body of science re: FCC's RFR limits and concluded 5G is safe.
- In turn, on September 20, 2019, Representatives Eshoo and Senator Jeff Merkley sent a letter[13] to a constituent that *"the agency concludes that the current RFR safety limits for cellphones are acceptable to protect public health. These conclusions hold for 5G technologies."*

As substantiated in detail in this Declaration, the elected officials' statements are inaccurate because the FDA has not made public any science based analysis of the FCC's RFR limits, nor shown any systematic review of the full body of research on health effects from wireless, much less 5G.

FDA's Misrepresentations Allows Policy Fast Tracking 5G into Neighborhoods and Wireless Networks into Schools: The FDA's misrepresentations have led to policy that allows the unchecked proliferation of 4G/5G wireless devices and infrastructure - millions of new "small cell" installations in close proximity to U.S. homes and schools. Officials at every level of government ignore calls for protective policy because of the FDA's false safety assurances.

As one of several examples, Montgomery County Maryland Councilman Hans Riemer, who pushed legislation allowing 5G cell antennas" at 30 from homes and schools without routine notice of public hearing- a common type of industry friendly policy being financed in local municipalities- repeatedly discussed how federal agencies had reviewed the science and determined 5G cell towers were safe- reiterating FDA's misinformation in tweets, facebook posts, statements during Council meetings and newsletters to his constituents.

As an example, Councilman Riemers July 28, 2021 newsletter reads:

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[11] "U.S. Senator Richard Blumenthal and U.S. Representative Anna G. Eshoo (CA-18) Letter to Federal Communications Commission Commissioner Brendan Car About 5G Health Hazards," December 9, 2018,
[12] "FDA Response to Representative Eshoo," September 9, 2019.
[13] "U.S. Senator Richard Blumenthal and U.S. Representative Anna G. Eshoo (CA-18) Letter to Federal Communications Commission Commissioner Brendan Car About 5G Health Hazards." December 9, 2018.

> **"What do leading public health authorities say about cell phones and 5G?**
> Safety comes first. Fortunately, the science on wireless waves is compelling. The leading national and international scientific institutes continue to find that cell phones are not linked to health problems. The FDA, which we are proud to have located here, reviews the existing studies and puts them all into a balance. The FDA clearly says, the "weight of scientific evidence has not linked cell phones with any health problems."

False Narrative Repeated by Other Federal Agencies: Health and safety agencies reference the inaccurate FDA information reiterating a false narrative of safety.

For example in June 2020, the National Cancer Institute released an article on the FDA Literature Review that was titled "FDA Says Data Doesn't Link Cell Phones to Cancer" that says, *"Is there any reason to worry? The best evidence says no."*
The National Cancer Institute's Cell Phone Radiation page references the FDA rejection of the NTP and states, "*The US Food and Drug Administration (FDA) notes that studies reporting biological changes associated with radiofrequency radiation have failed to be replicated and that the majority of human epidemiologic studies have failed to show a relationship between exposure to radiofrequency radiation from cell phones and health problems."*

A heartbreaking example of how the FDA's misleading information leads to false safety assurances that are then amplified by government agencies which in turn impacts the public can be found in the case of the Middle school student who wrote a US government scientist requesting a campaign for safer cell phone use in light of the NTP study findings of cancer in 2016.

NCI was sent a letter by a Middle Schooler asking why the agency are not starting a campaign for safe cell use *"For my final project I am researching about the health effects of radiofrequency radiation given off by cell phones. As seen through your research the radiofrequency radiation given off by cell phones can cause cancer and or tumors in the head, neck and heart lab rats. However there are no PSAs or any commercials to inform the public about this topic which is why I am writing to you."*

In response the National Cancer Institute wrote back, *"We hope you will understand that, as a research agency, the National Cancer Institute does not conduct public awareness campaigns. In addition, the US Food and Drug administration shares responsibility for cell phones with the FCC. Although cell phones can be sold without FDA clearance or approval the agency monitors the effects the phones have on health. FDA has the authority to take action if cell phones are shown to admit RF energy at a level that is hazardous to the user."*

The letter could have been a pivotal moment when the NCI and NIH considered the need for more public information on how to reduce cell phone radiation. Instead, this student was sent to

the FDA website and provided information downplaying the study findings rather than encouraged.

Armed Forces Falsely Reassures Service Members : Members of our armed forces are using numerous wireless devices as part of their job and due to the FDA's information will remain unaware of any potential health effects they might be experiencing. As an example, the U.S. Army Public Health Command has a cell phone fact sheet that references the FDA as periodically reviewing the research, stating:

> "*Who decides whether cell phones are safe? Subject matter experts from the Food and Drug Administration (FDA), the Federal Communications Commission (FCC), the Environmental Protection Agency, the National Cancer Institute, the Department of Defense, the Institute of Electrical and Electronics Engineers (IEEE) and others periodically review the research data to see if there are any potential health effects from RFR... These agencies have declared publicly that cell phones conform to published standards and are safe.*"

The Media Amplifies Expands the False Illusion of Safety: The media, the public, government officials, medical professionals and even the Courts are provided false safety assurances and repeat and amplify the FDA's misrepresentations with additional unfactual information they assume to be true. The FDA does not offer corrections to the clear false statements that were borne of the FDA misrepresentations. Because media references the FDA's misrepresentations as a source of credible information and the public believes safety is assured.

In 2018, CNN, Scientific American, Reuters, New York Times, Science, Forbes and Medscape all featured how the FDA ``disagreed" with the "clear evidence of cancer" conclusions of the National Toxicology Program. Medscape's headline exemplified the media coverage: "Cancer Fears Over Cell Phones, Again, but FDA Disagrees." The Verge coverage read, "the FDA is still confident that the current limits on cell phone radiation are safe." The Daily Mail headline read, *"FDA insists cell phones ARE safe - despite new government study that found 'clear evidence' of link to heart and brain cancers in rats' '.*

Court Proceedings Hinge on FDA's Misrepresentations: The FDAs misleading presentations have led to major court rulings in favor of industry and against our right to know. As an example, the FDA has repeatedly asserted there is a "large safety margin" for cell phone radiation limits and then followed with a sentence about how RFR limits have a 50 times safety factor. However, the FDA never clarifies that they are in fact referring to *two different types of regulations, confusing the reader.* While both of these FCC regulations are based on the *heating is the only harm* assumption (proven wrong by the NTP study and other research not adequately reviewed by the NTP), even if this assumption were true, the cell phone FCC premarket cell phone radiation test localized regulatory limits **do not have a 50 fold safety factor for brain tissue** as a factual matter.

However due to the FDA misrepresentations of the safety factor and its misrepresentation that it evaluated the scientific evidence and adequacy of FCC limits, the FCC and even the wireless companies put forward inaccurate information, thinking it is accurate based on the FDA's misleading statements.

For example, in court proceedings for Cohen v. Apple, APPLE's brief inaccurately stated that there is a "50-times" safety factor for local cell phone radiation limits. This inaccurate information combined with the FCC's "safety determination" led to the Court's ruling in favor of Apple.

A transcript from the hearing on November 21, 2019 has wireless companies asserting that the FDA has provided expertise to the FCC regarding RF safety which most will assume means that the FDA has come to an official safety determination through scientific review of the evidence.

Statements made on november 21 2019 by Samsung's Lawyer

> "Your Honor, Rob Katerberg for Samsung. Our phones are 100 percent compliant with the FCC standard for radio frequency emissions. The FCC has studied this issue extensively over a number of years. They have consulted with the FDA, which is an expert agency on human health effects."
>
> "The NTP study, that National Toxicology Program study that Counsel referenced, a few days after it came out, the FDA put out a press release saying that the findings of that study are not to be extrapolated to humans. It was a study on laboratory rodents."
>
> "And you will see that when it [referring to a phone] is actually tested in the way that the FCC has prescribed, every one of those results comes in under -- well under the 1.6 watts per kilograms standard of the FCC. This is an area in which the FCC has extensive expertise and has worked with the FDA, and our phones fully comply with that process."

On December 4, 2019—after reviewing more than 1,000 comments, from 564 commenting agencies and experts,25 and discussing with other federal agencies, particularly the FDA—the FCC declined to modify its RF testing and exposure limits, and instead reaffirmed them as the appropriate measure. The FCC explained it "t[ook] to heart" the FDA's findings that "the weight of the scientific evidence has not linked cell phones to any health problems." 26 Specifically, the FCC observed that "no expert health agency expressed concern about the Commission's RF exposure limits." 27 The FCC concluded that "no scientific evidence establishes a causal link between wireless device use and cancer or other illnesses." 28

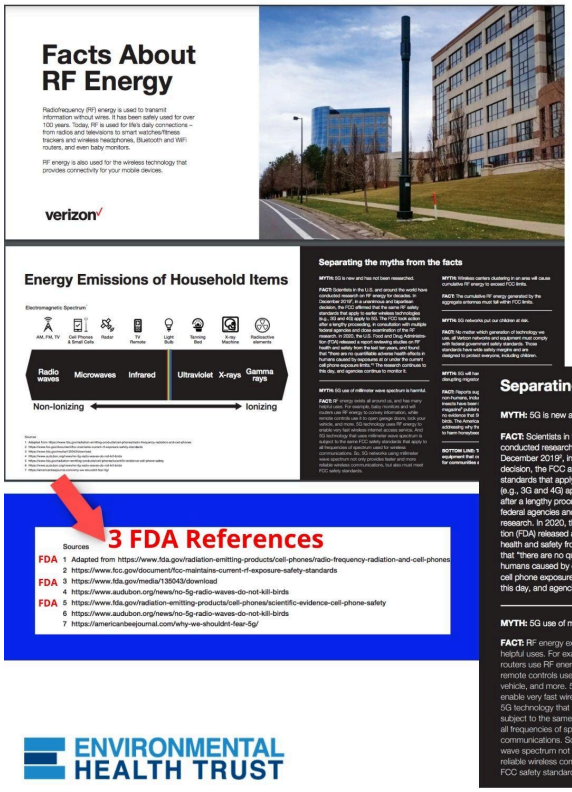
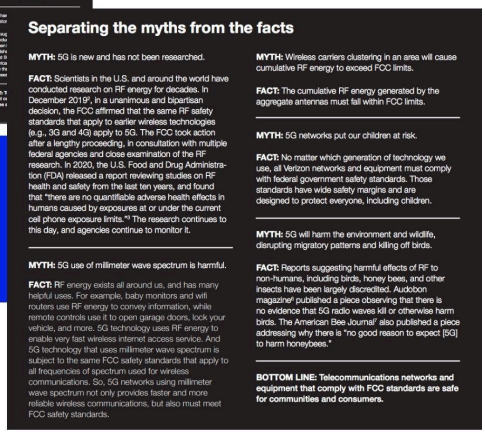
In **Wireless Ass'n v. City of Berkeley** the FDA's misleading information was again used by the FCC in their statement to the Court effectively halting implementation of the Berkeley Cell Phone Right To Know law. On September 17, 2020, the Court found the Berkeley Ordinance preempted by the FCC's 2019 RF limit affirmation because the FCC had determined that even if wireless devices produce RF exposure that would be in excess of FCC limits, the FDA had concluded that exposure would be well below levels considered dangerous. The September ruling specifically cited the FDA stating, *"The FDA maintains that 'the weight of scientific*

evidence has not linked cell phones with any health problems' and that 'the current safety limits for cell phones are acceptable for protecting the public health."

The Wireless Industry Avoids Accountability: The wireless industry is using the FDA's misrepresentation to shield themselves from accountability. Wireless companies are able to cite the FDA as proof of safety and avoid accountability in legal actions for harms to people and the environment from their RFR-emitting devices and networks. Wireless companies use the FDA and FCC limits to avoid regulations- such as Cities looking at setbacks for cell towers.

See below a table with key examples of how the FDA's contradictory and misleading information is used by the wireless industry to promote the false narrative that cell phones, Wi-Fi devices, cell towers and 5G have been deemed safe after a robust safety review by the FDA.

Wireless Industry Document	**Documentation on How FDAs Misrepresentations are Augmented, Expanded and Amplified into Sweeping Unsubstantiated Conclusions**
CTIA Consumer Website Wireless Health Facts- Wirelesshealthfacts.com	**FDA's Misrepresentations in CTIA Statements** #1: The FDA evaluated the "totality" of scientific data. #2: The FDA's Literature Review is a scientifically valid risk assessment. #6: The NTP study is irrelevant to human health. #7: The FDA has evaluated FCC's RFR limits. #8: The FDA "continuously monitors the science. **Statement by CTIA** *"**Are cellphones, cell towers, small cells and antennas safe?*** *[Answer] Radiofrequency energy from wireless devices and networks, including radiofrequencies used by 5G, have not been shown to cause health problems, according to the international scientific community. To cite one example, the Food and Drug Administration said. "Based on the FDA's ongoing evaluation, the available epidemiological and cancer incidence data continues to support the Agency's determination that there are no quantifiable adverse health effects in humans caused by exposures at or under the current cell phone exposure limits."* "*The Food and Drug Administration has also said that "the existing safety limits for cell phones remain acceptable for protecting the public health."* *"Cell phones don't cause cancer FDA says"* *"After reviewing the [National Toxicology Program] study, the Food and Drug Administration agreed, saying that "the existing safety limits for cell phones remain acceptable for protecting the public health."*

[Verizon's Consumer Information Page]	**FDA's Misrepresentations in Verizon Statements** #1: The FDA evaluated the "totality" of scientific data #10: Children and pregnant women are adequately protected by FCC RFR limits. **Verizon Statements** "*Do Wireless Phones Pose Any Special Risks to Children?: The FDA/FCC website states that 'the scientific evidence does not show a danger to users of wireless communication devices including children.'*"
Verizon's"Facts About RF Energy" brochure	**FDA's Misrepresentations in Verizon Statements** #1: The FDA evaluated the "totality" of scientific data #2: The FDA's Literature Review is a scientifically valid risk assessment. #8: The FDA "continuously monitors the science. #10: Children and pregnant women are adequately protected by FCC RFR limits. #13: The FDA scientifically reviewed the safety of 5G technology  
[Samsung's Health and Safety Information]	**FDA's Misrepresentations in Samsung Statement** #1: The FDA evaluated the "totality" of scientific data

	#3: The FDA has evaluated the science on specific non-cancer effects such as oxidative stress, impacts to reproduction and people with electromagnetic sensitivity. **Samsung Statements** "*The FDA publication includes the following information: Do cell phones pose a health hazard? Many people are concerned that cell phone radiation will cause cancer or other serious health hazards. The weight of scientific evidence has not linked cell phones with any health problems.*"
T -Mobile's RF Safety Webpage	**FDA's Misrepresentations in T-Mobile Statement** #1: The FDA evaluated the "totality" of scientific data #3: The FDA has evaluated the science on specific non-cancer effects such as oxidative stress, impacts to reproduction and people with electromagnetic sensitivity. #8: The FDA "continuously monitors the science. **T-Mobile Statements** *"Based on scientific data currently available, T-Mobile has not determined that RF energy from wireless phones causes health risks. Nonetheless, we want our customers to be informed as the wireless industry and government agencies continue to monitor the ongoing scientific research on this important subject."* *"The FDA, based on current data, "believes that the weight of scientific evidence does not show an association between exposure to radiofrequency from cell phones and adverse health outcomes."*
AT&T's Information on Wireless and Health Webpage	**FDA's Misrepresentations in AT &T Statement** #1: The FDA evaluated the "totality" of scientific data #3: The FDA has evaluated the science on specific non-cancer effects such as oxidative stress, impacts to reproduction and people with electromagnetic sensitivity. **AT &T Statement** "*The U.S. Food and Drug Administration (FDA) also has authority and expertise with respect to radio frequency fields and health, and has provided the FCC its expert views. The FDA concludes on its website: 'The weight of scientific evidence has not linked cell phones with any health problems.*"

Crown Castle 2021 Understanding the Safety of 5G	**FDA's Misrepresentations in Crown Castle Statement** #1: The FDA evaluated the "totality" of scientific data #7: The FDA has evaluated FCC's RFR limits. #9: There is "scientific consensus" that RFR radiation is safe. #13: The FDA scientifically reviewed the safety of 5G technology **Crown Castle Statement** "*The research is clear. The consensus of nearly seven decades of research by many of the top scientific and health communities, including the FDA, is that electromagnetic emissions at the levels allowed by FCC regulations are safe."*
GSMA Handbook on 5G, EMF Exposure and Safety The GSM Association is an industry organisation that represents the interests of mobile network operators worldwide.	**FDA's Misrepresentations in GSMA Statement** #1: The FDA evaluated the "totality" of scientific data #13: The FDA scientifically reviewed the safety of 5G technology **GSMA Statement** Under the section *'Is 5G Carcinogenic"* *"In February 2020 , the US Food and Drug Administration in a review of animal and epidemiological studies of radio signals and cancer concluded that:* *"To date there is no consistent or credible evidence of health problems caused by the exposure to radio frequency energy emitted by cell phones".'*
EMF Explained- A Website of the **Australian Mobile Telecommunications Association** - Webpage "US National Toxicology Program Study Results Published"	**FDA's Misrepresentations in Australian Mobile Telecommunications Association Statement** #1: The FDA evaluated the "totality" of scientific data #7: The FDA has evaluated FCC's RFR limits. #6: The NTP study is irrelevant to human health. **Australian Mobile Telecommunications Association Statement** *"The Food and Drug Administration (FDA) has reviewed the NTP report and issued a statement* *We respect the recently released research conducted by our colleagues at the National Toxicology Program (NTP), which is part of the National Institute of Environmental Health Sciences within the National Institutes of Health, on radiofrequency energy exposure. When we nominated this topic for study in 1999, there were limited epidemiological and long-term animal studies investigating the effects of radiofrequency energy exposure from cellular phones. Fortunately, since then, there have been hundreds of studies from which to draw a wealth of information about*

	these technologies which have come to play an important role in our everyday lives. *Taken together, all of this research provides a more complete picture regarding radiofrequency energy exposure that has informed the FDA's assessment of this important public health issue, and given us the confidence that the current safety limits for cell phone radiation remain acceptable for protecting the public health.* *Click here for the FDA statement"*
Verizon Improve Your Wireless North Carolina https://improveyourwireless.com/northcarolina/	**FDA's Misrepresentations in Verizon Statements** #1: The FDA evaluated the "totality" of scientific data #8: The FDA "continuously monitors the science. #10: Children and pregnant women are adequately protected by FCC RFR limits. #13: The FDA scientifically reviewed the safety of 5G technology **Verizon Statement** *"Are small cells safe?* *The Federal Communications Commission, in consultation with multiple federal agencies, sets federal government safety standards regarding small cells. Those standards have wide safety margins and are designed to protect everyone, including children, and were established after close examination of research that scientists in the US and around the world conducted for decades. The research continues to this day, and agencies continue to monitor it. Scientists have studied potential health effects of RF emissions from cell phones for decades. Based on all the research, federal agencies have concluded that equipment that complies with the safety standards poses no known health risks. And advisers to the World Health Organization have specifically concluded that the same goes for 5G equipment. In fact, the RF safety standards adopted by the United States Federal Communications Commission (FCC) are even more conservative than the levels adopted by some international standards bodies.* *FCC: The FCC provides information about the safety of RF emissions from cellular base stations on its website at: http://www.fcc.gov/oet/rfsafety/rf-faqs.html.* *FDA: The Food and Drug Administration's Cell phone website…"*
VERIZON PUBLIC HEARING ON 9/22/21 AT 6PM Glendale California: 9/22/21 testimony	**FDA's Misrepresentations in Verizon Hearing** #1: The FDA evaluated the "totality" of scientific data #7: The FDA has evaluated FCC's RFR limits. #9: There is "scientific consensus" that RFR radiation is safe. **Statements on Record** *" The RF exposure limits were set by the FCC in 1996, at the direction of Congress, and were reaffirmed in 2019. All FCC-regulated small cells*

	must comply with the FCC's RF limits. As such, ExteNet's installations adhere to those standards. The public limit incorporates a fifty times safety factor, that is, the limit is set fifty times below the level where the scientific consensus shows that there may be observable effects on humans. So, with the large safety factor in place, there are anticipated no observable effects at sites that are below the FCC limits... In addition, many household items, including microwave ovens, wireless modems, and televisions emit RF emissions and are deemed safe for everyday consumer use by the U.S. Food and Drug Administration."
Smartlink LLC on behalf of AT and T, for City of Independence California, Staff Report May 27, 2020	**FDA's Misrepresentations in Smartlink Statement** #1: The FDA evaluated the "totality" of scientific data #7: The FDA has evaluated FCC's RFR limits. #8: The FDA "continuously monitors the science. **Smartlink Statement** *"The FCC regulates RF emissions to ensure public safety. Standards have been set based on peer reviewed scientific studies and recommendations from a variety of oversight organizations, including the National Council on Radiation Protection and Measurements (NCRP), American National Standards Institute (ANSI), Institute of Electrical and Electronics Engineers (IEEE), Environmental Protection Agency (EPA), Federal Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), and National Institute for Occupational Safety and Health (NIOSH).* ***Although the purview of the public safety of RF emissions by the FCC was established by the Telecommunications Act of 1996, these standards remain under constant scrutiny.** All AT&T cell sites operate well below these standards, and the typical urban cell site operates hundreds or even thousands of times below the FCC's limits for safe exposure."*
Wireless Infrastructure Association (WIA) Wireless Networks and Your Health: THE FACTS	**FDA's Misrepresentations in WIA Statement** #1: The FDA evaluated the "totality" of scientific data #8: The FDA "continuously monitors the science. **WIA Statement** ***"The U.S. Food and Drug Administration has determined that based on all available evidence, there is "no increased health risk due to radio-frequency (RF) energy."*** *U.S. Food and Drug Administration, Consumer Updates:* *No Evidence Linking Cell Phone Use to Risk of Brain Tumors"*
Verizon Wireless	**FDA's Misrepresentations in Verizon Statement**

Letter to City of Salem Massachusetts 1/26/2021	#1: The FDA evaluated the "totality" of scientific data #8: The FDA "continuously monitors the science. **Verizon Statement** *"You also expressed concerns about the health effects of RF emissions from Verizon's network equipment. The FCC has developed safety rules for human exposure to RF emissions in consultation with the numerous other federal agencies including the Environmental Protection Agency, the FDA and the Occupational Safety and Health Administration.… the FCC supported an adopted the standards after examining the RF research that scientists in the US and around the world conducted for decades.* ***Research continues to this day and agencies continue to monitor it. Based on that research, federal agencies have concluded that equipment that has been deployed in a manner that complies with the safety standards poses no known health risks."***
Jerrold Bushberg "Introduction to Potential Health Considerations of 5G Networks" at the Beverly Hills California Health and Safety Commission Meeting on February 24, 2020 (See Agenda, Watch video, See full transcript)	**FDA's Misrepresentations in Jerrold Bushberg Statement** #1: The FDA evaluated the "totality" of scientific data #3: The FDA has evaluated the science on specific non-cancer effects such as oxidative stress, impacts to reproduction and people with electromagnetic sensitivity. #8: The FDA "continuously monitors the science. Minute 1:18:00 *" It is fortunate that this [referring to the FDA] recently came out a week or so ago. It's the most recent review of all the epidemiological and animal data from the FDA and they ended with their conclusions they had these bullet points which said the FDA doctors scientists and engineers continuously monitor scientific studies and public health data for evidence that radiofrequency from cell phones could cause adverse health effects. To date there is no credible scientific evidence of health problems caused by exposure to radiofrequency energy."*
Industry consultant Jerrold Bushberg's testimony March 24, 2015 to Los Angeles County	*"The facts as presented by experts, the American Cancer Society, the World Health Organization, the Food and Drug Organization among others. Each of these organizations have concluded that LA Rics Site [RFR] signals are not a health concern. The RF waves will not case DNA damage or health problems"*
Jerrold Bushberg's June 8, 2017 testimony to San	*"On August 9, 1996, the Federal Communications Commission (FCC) established a RF exposure standard that is a hybrid of the current ANSI*

Anselmo, CA on cell tower health effects	*and NCRP standards...The FCC received thousands of pages of comments over a three-year review period from a variety of sources including the public, academia, federal health and safety agencies (e.g., EPA & FDA) and the telecommunications industry. The FCC gave special consideration to the recommendations by the federal health agencies because of their special responsibility for protecting the public health and safety. In fact, the maximum permissible exposure (MPE) values in the FCC standard are those recommended by EPA and FDA."* Bushberg presented nearly identical testimony over the years to numerous officials re health and safety in May 8, 2019 to Town of San Anselmo, July 18, 2015 to Oakland CA City Planning Commission, October 15, 2015 to Palo Alto CA, March 6, 2015 to Crown Castle on San Francisco wireless facilities, April 13, 2013 to Town of Ross, City of Laguna Beach March 14, 2007

The Medical Community is Unaware: Webmed, Medical Express and Healio Hematology/Oncology all feature stories about the FDA's finding of *"insufficient"* evidence. Exemplifying these, MD Edge Hematology and Oncology's 2020 article is entitled, *"FDA: Cell phones still look safe."* As an example, the American Cancer Society (ACS) cites the FDA's Literature review conclusion of "*insufficient evidence*" on its "cell phone radiation webpage" despite the fact that it is not a systematic review, not a risk assessment, nor a hazard identification study. In turn doctors do not routinely assess their patients' RFR exposure nor educate them on how to reduce exposure.

The Public Is Left in the Dark: The public is making choices about how they personally use technology based on these myths. Although they are concerned about the health impacts from widespread and ever-increasing exposure to wireless radiation, they are also easily confused about this highly technical issue. The first thing most people do it look up what government agencies such as the FDA state about safety issues. Most will feel a false sense of security from FDA's website on "cell phone safety." Thus, the public continues to purchase and use more and more wireless devices unaware of the serious health risks posed by years of chronic exposure. The public's confusion is compounded by the wireless industry's safety assurances - substantiated by the FDA's misrepresentations.

We show in this Declaration that the FDA's misrepresentations and wide-spread dissemination of factual errors are at the very heart of the misinformation causing confusion and false assurances of wireless exposure safety. The continued failure by the FDA to clarify its EMF activities and level of review is leading to serious, catastrophic consequences as well as high financial costs.

A Remedy Is Needed As the FDA's Failure to Act Will Lead To Continued Harm

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I. FDA's Contradictory Statements, Misrepresentations and Lack of Clarifications Regarding its Policy

This Declaration contends that FDAs misleading information is helping cause an imminent hazard to the American public by allowing an unprecedented increase to RFR/EMF exposure.

FDA Misrepresentation #1: The FDA evaluated the "totality" of scientific data to make a determination that 1. There are no health effects from cell phone radiation; and 2. That FCC Radio Frequency Radiation (RFR) limits are adequately protective and do not need to be changed.

Fact: The FDA has not publicly released any reports or systematic reviews that show the FDA has reviewed all health effects. The one report the FDA did release in 2020 is simply a literature review filled with inaccurate statements the FDA refuses to correct despite numerous letters by experts including longtime NIH scientists. This literature review is scoped to cancer and did not review studies on other health effects so it cannot be presented as a literature review on the totality of studies. More importantly, the 2020 literature review is not a systematic review nor a health risk assessment nor a risk assessment nor a risk characterization report. Yet the FDA's literature review is misleadingly presented by FDA communications as scientific documentation that there are no "health problems."

The FDA repeatedly presents this misrepresentation to the public on its website, to Congressional officials and scientists. The FDA does not inform members of Congress or the public that the FDA literature review is limited to only cancer (not memory problems, brain damage or sperm damage) and cell phones (not Wi-Fi, Bluetooth or 5G small cells or cell

towers). If the FDA has indeed performed a systematic review of the totality of the research, it has not been made available to the public at this time.

The FDA also omits that no federal agency is actively reviewing the science on 5G modulation or cell tower radiation. The FDA also omits that it has not evaluated the research on magnetic fields and extremely low frequency fields, a type of non ionizing radiation from cell phones and electronic products. When people place devices on their chest or lap or body, they are exposed to these fields as well as radio frequencies.

Sections

1. Examples of FDA's statements asserting the FDA evaluates the totality of the scientific data.
2. Examples where the FDA presents that they evaluated the "totality of the data but then only presents documentation of a literature review scoped to cancer, confusing the reader and creating the illusion that the FDA's "review" was about all health endpoints.
3. Documentation that the FDA is misrepresenting that it reviewed the"totality" of the science on radiofrequency radiation.

Examples of FDA's statements asserting the FDA evaluates the totality of the scientific data

The FDA's online webpage "Do Cell Phones Pose a Health Hazard?"[14] states

> *"Based on the evaluation of the currently available information, the FDA believes that the weight of scientific evidence has not linked exposure to radio frequency energy from cell phone use with any health problems at or below the radio frequency exposure limits set by the FCC."*
>
> *"The available scientific data on exposure to radio frequency energy show no categorical proof of any adverse biological effects other than tissue heating."*
>
> *"The FDA's physicians, scientists, and engineers regularly analyze scientific studies and publications for evidence of health effects of exposure to radio frequency energy from cell phones. The weight of nearly 30 years of scientific evidence has not linked exposure to radio frequency energy from use of cell phones to health problems, such as cancer."*

The FDA's webpage "Scientific Evidence for Cell Phone Safety"[15] states:

> *"The currently available epidemiological studies, public health surveillance data, and supportive laboratory studies on cell phone radiation provide abundant evidence to support the FDA's determination." This statement would be interpreted by most readers to mean they looked at all the available data.*

[14] "Do Cell Phones Pose a Health Hazard?" U.S. Food and Drug Administration. (2020) https://www.fda.gov/radiation-emitting-products/cell-phones/do-cell-phones-pose-health-hazard

[15] "Scientific Evidence for Cell Phone Safety." U.S. Food and Drug Administration. (2020) https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety.

On the same page the FDA references its 2020 released Literature Review but never states in the description of the report that it is scoped to cell phone and cancer. The FDA states:

> *"To date, there is no consistent or credible scientific evidence of health problems caused by the exposure to radio frequency energy emitted by cell phones (see Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer – PDF 1.3MB)."*

The FDA's webpage "Children and Teens and Cell Phones"[16] states:

> "Current scientific evidence does not show a danger to any users of cell phones from radio frequency (RF) energy, including children and teenagers" creating the illusion that the FDA has considered the "current scientific evidence."

The 2/02/2024 online statement by Dr. Shuren states:

> "there have been hundreds of studies from which to draw a wealth of information about these technologies which have come to play an important role in our everyday lives. Taken together, all of this research provides a more complete picture regarding radiofrequency energy exposure that has informed the FDA's assessment of this important public health issue, and given us the confidence that the current safety limits for cell phone radiation remain acceptable for protecting the public health."

The 11/1/2019 online statement by FDA's Dr. Shuren[17] about the NTP study states:

> "After reviewing the study, we disagree, however, with the conclusions of their final report regarding "clear evidence" of carcinogenic activity in rodents exposed to radiofrequency energy."
>
> "Based on our ongoing evaluation of this issue, the totality of the available scientific evidence continues to not support adverse health effects in humans caused by exposures at or under the current radiofrequency *energy exposure limits. We believe the existing safety limits for cell phones remain acceptable for protecting the public health."*

On September 9, 2019: The FDA sent a letter to Representative Anna Eshoo and Jeff Merkley stating in the letter and section on "FDA's findings" that;

> *"The agency has taken a comprehensive approach to evaluating scientific evidence regarding the impact of RFR exposure on human health. In the attached summary, FDA explains the critical considerations that we have made in evaluating all available information on this and other related topics"* and *"the available epidemiological and*

[16] "Children and Teens and Cell Phones." U.S. Food and Drug Administration. (2020) https://www.fda.gov/radiation-emitting-products/cell-phones/children-and-teens-and-cell-phones.

[17] "Statement from Jeffrey Shuren, M.D., J.D., Director of the FDA's Center for Devices and Radiological Health on the National Toxicology Program's Report on Radiofrequency Energy Exposure." U.S. Food and Drug Administration. November 01, 2018. https://www.fda.gov/news-events/press-announcements/statement-jeffrey-shuren-md-jd-director-fdas-center-devices-and-radiological-health-national.

cancer incidence data continues to support the Agency's position that there are no quantifiable adverse health effects in humans caused by exposures at or under the current cell phone exposure limits."

"FDA considers all relevant scientific data on RFR and does not limit its considerations to any specific frequency or modulation due to the increasing use of, for example, Wi-Fi enabled medical devices."

Note: this FDA letter was in response to a July 18, 2019 letter from Eshoo and Merkley[18] asking for a "Summary of the Research" used by the FDA and FDA criteria used to determine which studies the FDA has reviewed because "hundreds of constituents have contacted our offices."

A March 14, 2019 letter from FDA's Jeffrey Shuren to Dr. Ronald Melnick[19] states;

"We must thoroughly evaluate and take into consideration the totality of the data"

Examples where the FDA presents that they evaluated the "totality of the data" but then only presents documentation of a literature review scoped to cancer.

The FDA often states it evaluates the "totality of the evidence" but then later in its letters or statements the FDA references how it scoped its literature review only to cancer and cell phones. However, most readers will not be aware that effects have been found for numerous non-cancer health effects, and the end result is that the reader will think all the science is evaluated.

Examples where the FDA talks about the totality of the science but then later cites only their consideration of cancer and cell phones:

The FDA 2020 Literature Review on Cancer[20] states in its executive summary that:

"*The Agency has taken a comprehensive approach to evaluating the available scientific evidence regarding the impact of radiofrequency radiation (RFR) exposure on human health."*

[18] "EHT letter to Eshoo and Merkley regarding FDA RF errors." October 18, 2019. https://ehtrust.org/wp-content/uploads/October-18-2019-Letter-to-Eshoo-in-Response-to-FDA-Letter-on-RF-and-5G-Safety-Final.pdf.
[19] "FDA response letter to Dr. Ronald Melnick." March 14. 2019. https://ehtrust.org/wp-content/uploads/Dr.-Shuren-Response-Scientists-March-14-2019.pdf.
[20] "Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer." (February 2020) https://www.fda.gov/media/135043/download.

A September 8, 2020 letter from the FDA Office of Legislation[21] to the office of Senator Tammy Baldwin states:

> *"The Food and Drug Administration (FDA or the Agency) has recently publicly released a considerable amount of information that details the evaluation of scientific evidence related to the safety of cell phone handsets. Specifically, the Agency has conducted and published a detailed literature review of all scientific evidence that has become available for over the past decade, and updated our web pages related to all aspects of radiofrequency radiation from cellphones."*
>
> "*The Agency will, of course, take these comments into consideration as we continue to monitor all available relevant information."*

The FDA states that *although their focus is on cancer*, the FDA considers "all" concerns despite no evidence documenting FDA's systematic evaluation of "all" the evidence.

This is exemplified in the FDA letter to Representative Anna Eshoo and Senator Jeff Merkley which only *after the section on FDA's findings that talks about "all" the science* (the only section most people will read) the FDA states that the FDA focuses mainly on cancer *"specifically because of public health concerns about possible effects of RFR emissions, although FDA considers all public health concerns that are discerned from FDA's evaluation of scientific evidence."*

Documentation that the FDA is misrepresenting that it reviewed the "totality" of the science on radiofrequency radiation.

The FDA has not publicly released any reports or systematic reviews that show the FDA has reviewed health effects other than cancer and furthermore the one report the FDA did release in 2020 is simply a literature review filled with inaccurate statements the FDA refuses to correct despite numerous letters by experts including longtime NIH scientists. Importantly, the 2020 literature review is not a systematic review nor a risk assessment. If the FDA has performed a systematic review of the totality of the research, it has not been made available to the public.

1. **Government Accountability Office (GAO):** The GAO 2020 Report on 5G[22] confirms the fact that the FDA did not include non cancer outcomes starting on page 44:
   > "the FCC relies on the FDA as well as other organizations—principally IEEE and the National Council on Radiation Protection and Measurements (NCRP)—to

[21] "FDA letter to Representative Anna Eshoo and Senator Jeff Merkley". (September 8, 2020) https://ehtrust.org/wp-content/uploads/FDA-9_10_-2020-Letter-Senator-Tammy-Baldwin-.pdf.

[22] US Government Accountability Office, 5G Wireless: Capabilities and Challenges for an Evolving Network. *U.S. GAO*. (November 24, 2020). https://www.gao.gov/products/gao-21-26sp.

review scientific research and provide recommendations for setting RF safety standards. However, each of these organizations has only reviewed a subset of the relevant research...According to officials, the FDA monitors peer-reviewed science regarding RF energy and health. The agency does not typically make its assessments publicly available, but released one assessment publicly in February 2020. The [FDA] assessment focused on cancer-related animal and human studies of frequencies below 6 GHz. The [FDA] assessment did not include non-cancer outcomes or frequencies above 6 GHz."

2. **FDA's Literature Review (2020):** The FDA has only shown one research-based report- the 2020 Literature Review- in the last decade that is *focused solely on cell phones and cancer.* (Note: numerous scientists have criticized this FDA report for scientific shortcomings, as is discussed later.) The FDA has never shown any systematic evaluation of the full body of science that includes non-cancer impacts such as electromagnetic sensitivity, memory problems or impacts to brain development, and reproduction.

3. **FDA Authority Inapplicable to 5G Small Cells of Cell Tower Exposures:** The FDA has never shown any systematic evaluation of the full body of science related to the low-level chronic environmental exposures ***from cell towers'*** and base stations' antenna(s) (i.e., "small" cell antenna 4G and 5G networks)—a body of literature different from that of just cell phones. Further, as the FDA is only under authority to address cell phones and consider devices, there is currently no U.S. federal agency monitoring the RFR levels from cell tower networks, systematically reviewing the science on environmental exposures and ensuring the public and wildlife are protected. The FDA never highlights this gap.

For years, the FDA has been unable to clarify if it had any type of formal review process regarding the science as well as FCC limits.

On July 14, 2014, Scarato was scheduling an in-person meeting at the FDA and asked in an email, "Is there a current FDA group that is currently analyzing the current science on RF radiation?" and on July 22, in response FDA stated, "The primary people that follow the current science of RF radiation at CDRH are Dan Kassiday and me. We do have a small group that works with us on this issue. However, like Dan and me, they have other duties as well."

In 2016 after several requests about a formal review process, the FDA's Kassiday stated,[23] *"FDA did not conduct a formal meta-analysis nor a formal review of RF studies in 2013."*

In the same email chain, Scarato asks, *"Did the FDA specifically make a determination on the radio-frequency radiation public exposure limit and if it adequately protects human health?" and*

[23] "Email from the FDA to Theodora Scarato." (February 5, 2016) https://ehtrust.org/wp-content/uploads/FDA-Emails-no-FDA-review-.pdf.

*The FDA did not respond to that question. The refusal to respond to direct questions is a pattern seen in all the FDA communications referenced in this declaration (*VI. The FDA's Lack of Transparency and Refusal to Fully Respond to Questions and the Call for Corrections by the Public, Federal Officials and Scientists.)

2/5/2016 Scarato FDA email chain
Dear Ms. Scarato:

The FDA position has not recently changed. As we state on our cell phones web page: "The weight of scientific evidence has not linked cell phones with any health problems." Therefore, existing accepted radio frequency (RF) exposure limits, such as the limits in FCC regulations, provide adequate protection for everyone. We continue to monitor scientific literature regarding this topic for any indication of potentially significant evidence of adverse health effects. Thank you for providing the three papers in your email dated December 7, 2015 by Belyaev, Carlo, and Yakymenko.
FDA did not conduct a formal meta-analysis nor a formal review of RF studies in 2013. However, the WHO is in the process of updating their environmental health criteria (EHC) for RF. We expect the finished EHC monograph will include a formal meta-analysis covering research which was published after the cutoff date used in the 1993 EHC - http://www.who.int/peh-emf/research/health_risk_assess/en/index2.html. A relatively recent review of 30+ expert reports on RF which you might find informative is: Verschaeve Luc (2012). Evaluations of International Expert Group Reports on the Biological Effects of Radiofrequency Fields, Wireless Communications and Networks - Recent Advances, Dr. Ali Eksim (Ed.), ISBN: 978-953-51-0189-5, InTech, DOI: 10.5772/37762 which can be found at: http://cdn.intechopen.com/pdfs/31625/InTech-Evaluations_of_international_expert_group_reports_on_the_biological_effects_of_radiofrequency_fields.pdf

FDA jurisdiction related to exposure to radiofrequency radiation is from the Electronic Product Radiation Control (EPRC) provisions of The Federal Food, Drug, and Cosmetic Act (Act). This portion of the law can be found at: http://www.gpo.gov/fdsys/pkg/USCODE-2013-title21/pdf/USCODE-2013-title21-chap9-subchapV-partC.pdf. The EPRC provisions require that, "The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation." Please note that the term 'electronic products' is very broadly defined and covers any product which uses an electronic circuit to emit, or which would emit in the absence of safety measures, any form of radiation.

If you have more questions about that section of the law and FDA jurisdiction please contact me.

Daniel Kassiday
SME: Electronic Product Radiation Control
U.S. Food and Drug Administration / Center for Devices and Radiological Health /
Office of In Vitro Diagnostics and Radiological Health / Division of Radiological Health
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Daniel.kassiday@fda.hhs.gov

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

For general information about electronic products, please visit the FDA website http://www.fda.gov/Radiation-EmittingProducts/default.htm. For Accession number status, please call (301) 796-6627. For assistance with eSubmitter please write to: esubmitter@fda.hhs.gov. Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received. https://www.research.net/s/cdrhcustomerservice?O=500&D=560&B=564&E=&S=E

From: theodorams@aol.com [mailto:theodorams@aol.com]
Sent: Saturday, January 30, 2016 10:33 AM
To: Shuren, Jeff; Maisel, William; Mitchell, Diane A.; Sheldon, Murray
Subject: Question about the FDA and radiofrequency radiation

Hello,
I have written the FDA several times last month and received no answer so I am writing all of you in hopes someone can surely answer this question.

I am writing to ask the following question regarding radiofrequency radiation.

I was told "the Food and Drug Administration conducted a review as recently as 2013 and found that there is no basis to establish a different safety threshold." This is concerning radio-frequency fields. I was told the FDA did a review and made a determination.

I am sure the above statement is inaccurate but I need confirmation from you. I see no report that the FDA did on radio-frequency radiation.

Please answer the following questions

1. Could you please confirm if there was a "review"by the FDA. If so please send me the online link or attach documentation.
2. If such a review exists, how did the FDA make the determination? Which studies?
3. Did the FDA specifically make a determination on the radio-frequency radiation public exposure limit and if it adequately protects human health?
4. If the statement I have above in blue is false can you please confirm to me that no such "review exists"

Thanks so much- Theodora Scarato LCSW-C.

FDA Misrepresentation #2: The FDA's "Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer" released in 2020 is a scientifically valid risk assessment.

Fact: Although the FDA inaccurately states in its 2020 Literature Review that they "completed an updated radiofrequency (RF) exposure risk analysis," this literature review is riddled with major errors and not a scientifically defensible "risk analysis" based on the best practice guidelines for risk assessment developed by US scientists. Further, the FDA Literature Review was not a systematic review, nor a review of the adequacy of FCC limits. However the FDA misrepresents this review as substantiating its conclusions that FCC's limits do not need to be changed and the review is used on the FDA's web pages to substantiate the website page assertion that cell phones are safe. The FDA refuses to correct inaccurate date presented in this review.

The FDA also refuses to answer questions about the literature review such as what scientists wrote it and what scientists peer reviewed it. The only response regarding authorship was *"There is no authorship provided as the white paper is simply a summary of a literature review. The manner in which it was assembled is explained in the document."*

Sections

- Evidence that the FDA misrepresents that the literature review is an official risk assessment.
- The 2020 Literature Review is not a risk assessment but it is simply a literature review. This review did not follow US government scientists Best Practice guidelines for risk assessment.
- The FDA's 2020 Literature Review contained numerous errors that remain uncorrected.
- March 4, 2020 Letter to the FDA from Scientists with questions in regards to the FDA Literature Review
- Dr. Ronald Melnick Letter to FDA Jeffrey Shuren, M.D., J.D. February 27, 2020

Evidence that the FDA misrepresents that it has performed an official risk analysis or risk assessment.

The FDA's Office of Legislation 2020 letter to U.S. Senator Baldwin[24] states:

[24] "FDA's Office of Legislation 2020 letter to U.S. Senator Baldwin." (January 30, 2020). https://ehtrust.org/wp-content/uploads/FDA-9_10_-2020-Letter-Senator-Tammy-Baldwin-.pdf

> *"Based on this **extensive risk analysis,** our **determination remains consistent that there is no scientific evidence that warrants a change in cell phone safety limits,** and that there is insufficient evidence to demonstrate a causal link between cell phones and cancer in the population."*

The FDA's letter to Eshoo and Merkley creates the illusion that a risk assessment was done, stating:

> *"The gold standard for the **assessment of risk to public health** remains the data and information that is available from studying effects on humans. Animal and laboratory studies can provide useful scientific information, but data on human health is the most informative where it is available. In the case of cell phone handsets, there is abundant evidence to **support FDA's conclusion** from epidemiological studies, public health surveillance data and supportive laboratory studies. The information on which FDA has based its conclusion is summarized below, together with a description of the methods that the Agency uses for undertaking risk analysis and other relevant scientific information."*

The 2020 Literature Review did not follow US government scientists Best Practice guidelines for risk assessment.

The FDA states in its literature review that it completed a risk analysis, yet provided no documentation of the risk analysis.

> *"The FDA has completed an updated radiofrequency (RF) exposure risk analysis based on relevant peer-reviewed in vivo (animal) and epidemiological studies published from January 1, 2008 to August 1, 2018 for in vivo studies, and from January 1, 2008 to May 8, 2018 for epidemiological studies. This risk analysis was scoped to assess any possible causal relationship between RFR exposure and the formation of tumors. In this technical report we provide a detailed summary of the substantial body of scientific evidence that has informed our determination regarding potential adverse health effects in humans caused by RFR exposures and the risk analysis we performed."*

The FDA did not follow good practice recommendations for systematic review for risk assessment and hazard identification of environmental health exposures that have been developed and published by US government experts and international scientists (Whaley et al.,

2016[25], Whaley et al., 2020,[26] Rooney et al., 2014,[27] NAS, 2017[28], Stephens et al., 2016[29]). The U. S, Office of Health Assessment and Translation (OHAT) adapted guidance, principals and methods for systematic-review of environmental health questions (through consultation with technical experts in systematic review and human health assessments, as well as scientific advisory groups and the public) to provide greater objectivity and transparency to the process of developing conclusions. In health care, detailed methodologies with descriptions of strengths and discussions of nuances of scientific review steps have been developed by the International Cochrane Collaboration[30], and the U.S. Agency for Health Research Quality[31] (AHRQ), using methods that are summarized on the Preferred Reporting Items for Systematic Reviews and meta-Analyses (PRISMA) website (Moher et al., 2009[32], Liberati et al., 2009[33]). However the FDA did not show that it followed these methods.

In contrast to these published expert practice recommendations for review, the FDA's 2020 Literature Review did not show the FDA systematically compared FCC's limits to the effects found at various exposure levels in the full body of published scientific publications.

The FDA did not follow best practices. It did not not grade nor weigh the evidence, rate the level of confidence or translate that level into levels of evidence for health effects. The FDA did not publicly publish the protocol nor secure peer-review and public feedback. There are no explicit standards or protocols relied on for selecting and evaluating the studies, and no effort to meta-analyze them in any way. Nor did the FDA share which scientists were part of the evaluation, nor if they had been vetted for conflicts of interest. The FDA did not check accuracy in their numeric data utilising an appropriate transparent process.

Importantly, while it could be possible that such a risk analysis exists and it has been kept confidential, this documentation has *never* been shared with the public or scientists who repeatedly have requested it. The FDA should share its grading of the research and risk

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[25] Whaley, Paul, et al. "Implementing Systematic Review Techniques in Chemical Risk Assessment: Challenges, Opportunities and Recommendations." *Environment International*, vol. 92–93, July 2016, pp. 556–64. *ScienceDirect*, https://doi.org/10.1016/j.envint.2015.11.002.

[26] Whaley, Paul, et al. "Implementing Systematic Review Techniques in Chemical Risk Assessment: Challenges, Opportunities and Recommendations." *Environment International*, vol. 92–93, July 2016, pp. 556–64. *ScienceDirect*, https://doi.org/10.1016/j.envint.2015.11.002.

[27] Rooney, Andrew A., et al. "Systematic Review and Evidence Integration for Literature-Based Environmental Health Science Assessments." *Environmental Health Perspectives*, vol. 122, no. 7, Environmental Health Perspectives, July 2014, pp. 711–18. *ehp.niehs.nih.gov (Atypon)*.

[28] National Academies of Sciences, Engineering, and Medicine. *Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals*. Chapter 2. The National Academies Press, 2017. *National Academies Press*.

[29] Stephens, Martin L., et al. "The Emergence of Systematic Review in Toxicology." *Toxicological Sciences*, vol. 152, no. 1, July 2016, pp. 10–16. *Silverchair*.

[30] *About Cochrane Reviews* | *Cochrane Library*. Accessed 30 Nov. 2021.

[31] *Methodology*. AHRQ. (n.d.). Accessed 30 Nov. 2021.

[32] Moher, David, et al. "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement." *BMJ*, vol. 339, BMJ Publishing Group Ltd, 2009, https://doi.org/10.1136/bmj.b2535.

[33] Liberati, Alessandro, et al. "The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Health Care Interventions: Explanation and Elaboration." *PLOS Medicine*, vol. 6, no. 7, Public Library of Science, July 2009, p. e1000100. *PLoS Journals*.

analysis not only as a matter of good government, but to ensure confidence in the FDA's conclusions and in the US regulations for wireless devices.

The FDA's 2020 Literature Review contained numerous critical errors that remain uncorrected.

The FDA's 2020 Literature review contained critical errors and unsubstantiated conclusions according to Dr. Ronald Melnick and other scientists who called for a retraction of the Literature Review and wrote the FDA. The FDA as far as we know has not responded to these letters, nor made corrections to the document except for a March 24, 2020 one sentence letter by Dr. Shuren that said *"thank you for sharing your and your colleagues' concerns with us. We appreciate your feedback."*

- February 27, 2020 letter by Dr. Ronald Melnick, a 28-year NIH scientist documented the evidence showing the FDA's statements were inaccurate in respect to the data the FDA presents on the NTP findings. For example s Dr. Melnick explains:

"Lastly, the FDA document misstates the results of the genetic toxicology tests in animals from the NTP study. For example, the FDA document claims there were 'no statistically significant increases in DNA damage in female rats or either mouse sex' and the increases in DNA damage in male rats 'was not statistically significant,' when in fact there were significant increases and significant trends in DNA damage in the frontal cortex of male mice exposed to GSM or CDMA modulated RFR and in the frontal cortex and hippocampus of male rats exposed to CDMA (NTP TR-595)."

Melnick concluded, "In conclusion, the FDA document has serious flaws and inaccuracies, as well as omissions of relevant data. Hence, in consideration of public health, it is important that FDA immediately retract their review on radiofrequency radiation and cancer."

- Dr. Albert Manville, a wildlife biologist for the U.S. Fish & Wildlife Service for 17 years, now at Johns Hopkins University, stated in his February 2020 letter on the FDA's literature review conclusion that there was "no quantifiable adverse health effects in humans" concludes, "As a certified wildlife biologist and Ph.D. environmental scientist who has studied the impacts of radiation on migratory birds, other wildlife, and humans since the late 1990s, the statement credited to the FDA is preposterous, without any scientific credibility, and at a minimum deserves a retraction by the FDA."

- Victor Leach of the Oceania Radiofrequency Scientific Advisory Association (ORSAA) letter on the FDA review reads[34]: "the non-cancer bioeffects are omitted in the FDA review. The bioeffects that need to be considered are listed below in their respective categories. Effects found in any of these categories have the potential for long-term chronic health implications. The glaring question is 'Why has the FDA ignored these subject areas?': Altered Electrophysiology, Altered Enzyme Activity, Altered Protein Levels Audiological Effects, Autonomic Nervous System Effect Cardiovascular Effects, Cell Membrane Effects, Cellular Signaling Effect, Central Nervous System Effects Circulatory System Effects Dermal Effects, Gene Expression Changes Growth/Development Effects Learning Effects, Mitochondrial Effects Neurodegeneration, Neurological System Effects Neurotransmitter Effect Ocular Effects, Pregnancy Effects, Renal Effects, Salivary Gland Effects Skeletal Effects, Sleep Effects, Thyroid Effects

- Prof. Tom Butler, of the University College in Cork, Ireland, sent a letter to the FDA[35] with science-backed criticism of its literature review concluding, "There are too many question marks over this report for it to be accepted as valid and reliable by any reasonable person, let alone a member of the scientific community. Thus, one may ask if the FDA has failed in its statutory duty to protect public health by promulgating the falsehood that RFR is not a carcinogen?"

- Igor Belyaev, Ph.D., Dr. Sc. Head, Department of Radiobiology of the Cancer Research Institute, Biomedical Research Center of the Slovak Academy of Science, who also was a member of the RFR working group of the World Health Organization International Agency for Research on Cancer, sent a letter to the FDA[36] concluding, "the selective FDA review is not in line with the majority of the scientific community on the issue of RF EMF health effects." No response from the FDA.

- An additional letter signed by several distinguished scientists[37] called on the FDA to retract its 2020 Literature Review and to remove the 2020 revisions to the FDA website pages. Scientists who signed the letter include: Lennart Hardell, M.D., Ph.D., Professor Department of Oncology, Faculty of Medicine and Health, Örebro University, SE-701 82 Örebro, Sweden (retired), The Environment and Cancer Research Foundation Örebro, Sweden; Samuel Miham, M.D., former Head of the Chronic Disease Epidemiology Section, Washington State Department of Health; David Carpenter, M.D., Director of the Institute for Health and Environment at University of Albany's School of Public Health, former director of the Wadsworth Laboratory of the New York State Department of

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[34] *Victor Leach of ORSAA: Critical Review of the FDA 2020 Report | BRHP – Between a Rock and a Hard Place*. 2020, p. 6. Leach, https://ecfsapi.fcc.gov/file/10916520207299/Victor.

[35] "Letter to Jeffery Shuren, Director of the Center for Devices and Radiological Health, FDA from Tom Butler University of College Cork Ireland." (February 29, 2020) https://ehtrust.org/wp-content/uploads/Prof-Tom-Butler-Letter-to-Jeffery-Shuren-Director-FDA-2020.pdf.

[36] "Letter to Commissioner Hahn and Jeffrey Shuren, FDA from Igor Belyaev, PhD, Dr.Sc.". https://ehtrust.org/wp-content/uploads/Igor-Belyaev-Letter-to-the-FDA-on-Cell-Phone-Radiation-.pdf

[37] "An additional letter to Commissioner Hahn and Jeffrey Shuren signed by several distinguished scientists." (March 04, 2020). https://ehtrust.org/scientistsletter-calling-for-a-retraction-to-the-fda-report-on-cell-phone-radiation-and-cancer/.

Health; Henry Lai, Ph.D., Professor Emeritus, University of Washington, Seattle, WA; Alfonso Balmori, B.Sc., Biologist, Spain; Beatrice Golomb, M.D., Ph.D., Professor of Medicine, University of California, San Diego; Devra Davis, Ph.D., M.P.H. President of Environmental Health Trust, Fellow American College of Epidemiology, former founding Executive Director, Board on Environmental Studies and Toxicology, National Academies of Sciences, Engineering and Medicine; Hillel Baldwin, M.D., Fellow American Association of Neurological Surgeons; Anthony B. Miller, M.D., Professor Emeritus of University of Toronto and World Health Organization; Magda Havas, Ph.D., Associate Professor, Trent University; Prof. Suleyman Dasdag, Department of Biophysics, Medical School of Istanbul Medeniyet University, Istanbul,Turkey; André Vander Vorst, Dr. in Applied Sciences, Professor emeritus at Université catholique de Louvain, Belgium; Don Maisch, Ph.D., Australia; Paul Heroux, Ph.D., McGill University; Martin L. Pall, Ph.D., Professor Emeritus of Biochemistry and Basic Medical Sciences, Washington State University; Peter Hensinger, M.A.; Hugo Schooneveld, Ph.D., Former senior researcher, Wageningen University, the Netherlands; Dr. Monika Krout, Germany; Professor Elihu D. Richter, M.D., M.P.H. at the Occupational and Environmental Medicine Department at the Hebrew University-Hadassah School of Public Health and Community Medicine; Marc Arazi, M.D. of Phonegate Association; Marko S. Markov, Ph.D., author of major medical textbooks in bioelectromagnetics; Wenjun Sun, Ph.D., Professor, Bioelectromagnetics Key Laboratory,

March 4, 2020 Letter to the FDA from Scientists (PDF)

Re: Call for Retraction of Flawed FDA Literature Review on Cell Phones

Dear Honorable Commissioner Hahn, Honorable Secretary of Health and Human Services Alex Azar and
Dr. Shuren Director of the FDA Center for Devices and Radiological Health;

As experts in the field of bioelectromagnetics, we are writing to urge you to retract a recent flawed report entitled "Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer. Further, we ask you to remove and replace recent revisions to FDA websites that invoke this recent report as grounds for asserting that cellphone radiation has no known health effects, contrary to official reviews in other high-technology nations.

As many of us have detailed in letters sent to your offices, this report does not merit publication or posting on FDA's website as it represents a highly limited review of the literature, contains "numerous scientific errors" omitting important studies for review and including studies that have been rejected for their flawed methods, and fails to acknowledge official actions by governments in France, South Korea, Belgium, Cyprus, European Parliament and recommendations by the American Academy of Pediatrics and California Department of Public Health that have issued specific advice about why and how to reduce exposures to cellphones and other wireless

radiation sources. By dismissing scientific evidence of adverse effects and downplaying the need for individuals to take precautionary measures when using cell phones, the FDA review does not comport with the Agency's mission of protecting and promoting public health.

Contrary to what the report and FDA website assert, there is no "scientific consensus" that cell phone radiation and 5G are safe as evidenced by the official statements of hundreds of scientists and medical organizations.

An interdisciplinary panel of independent experts providing a systematic review of relevant literature on cell phones and wireless radiation and health should guide the agency in its policy recommendations. Further, this review should also consider growing evidence of environmental effects along with public health impacts of exposures and relevant policy developments.

Signed,
Ronald Melnick PhD, former National Institutes of Health Scientist
Lennart Hardell MD, PhD, Professor Department of Oncology, Faculty of Medicine and Health, Örebro University, SE-701 82 Örebro, Sweden (retired). The Environment and Cancer Research Foundation Örebro, Sweden
Samuel Miham MD, former Head of the Chronic Disease Epidemiology Section, Washington State Department of Health
David Carpenter MD, Director of the Institute for Health and Environment at University of Albany's School of Public Health, former director of the Wadsworth Laboratory of the New York State Department of Health.
Henry Lai, PhD, Professor Emeritus, University of Washington, Seattle, WA
Alfonso Balmori, BSc Biologist. Spain
Beatrice Golomb, MD PhD, Professor of Medicine, University of California, San Diego
Devra Davis, PhD, MPH President of Environmental Health Trust and Fellow American College of Epidemiology, former founding Executive Director, Board on Environmental Studies and Toxicology, National Academies of Sciences, Engineering and Medicine
Hillel Baldwin, MD, Fellow American Association of Neurological Surgeons
Dr. Anthony Miller, Professor Emeritus of University of Toronto and World Health Organization Senior Advisor to Environmental Health Trust
Prof. Tom Butler, University College, Cork, Ireland
Igor Belyaev, PhD, Dr.Sc.Head, Department of Radiobiology of the Cancer Research Institute, Biomedical Research Center of the Slovak Academy of Sciences
Magda Havas, Ph.D., Associate Professor, Trent University
Prof. Suleyman Dasdag, Department of Biophysics, Medical School of Istanbul Medeniyet University, Istanbul,Turkey
André VANDER VORST, Dr in Applied Sciences
Professor emeritus at Université catholique de Louvain, BELGIUM
Don Maisch, PhD, Australia
Martin L. Pall, PhD, Professor Emeritus of Biochemistry and Basic Medical Sciences, Washington State University
Peter Hensinger M.A.

Hugo Schooneveld, PhD, Former senior researcher, Wageningen University, the Netherlands.
Dr. Monika Krout, Germany
Professor Elihu D. Richter MD, MPH at the Occupational and Environmental Medicine Department at the Hebrew University-Hadassah School of Public Health and Community Medicine
Marc Arazi MD of Phonegate Association, France
Marko S. Markov PhD, author of major medical textbooks in bioelectromagnetics.
Wenjun Sun PhD, Professor, Bioelectromagnetics Key Laboratory, Zhejiang University School of Medicine, China
Denis L Henshaw, Fellow Collegium Ramazzini, Emeritus Professor of Human Radiation Effects, Atmospheric Chemistry Group, School of Chemistry, University of Bristol
Christos D. Georgiou, Ph.D. Professor Emeritus of Biochemistry, Biology Department University of Patras, Greece

Dr. Ronald Melnick Letter to FDA Jeffrey Shuren, M.D., J.D. February 27, 2020

RE: FDA Literature Review on Radiofrequency Radiation and Cancer

Dear Dr. Shuren,

I am writing this letter to detail major incorrect statements and omissions of relevant data in the FDA document titled “Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer.” I led the design of the National Toxicology Program’s (NTP) toxicity and carcinogenicity studies on cell phone radiation and I strongly believe that the anonymously written FDA document misrepresents the utility of the NTP study for assessing human health risks. In addition, the report’s casual dismissal of both the mechanistic findings and the numerous results from epidemiological studies that have shown increased cancer risks associated with exposure to radiofrequency radiation (RFR) are inconsistent with the FDA’s stated core mission “to protect and promote the public health.”

Regarding the NTP studies on cell phone RFR, an expert peer-review panel discussed the results for 3 days and concluded (NTP TR-595; Peer-Review Report 2018) that this carefully designed and conducted study provided “clear evidence of carcinogenic activity.” In contrast to the NTP and peer review conclusions, the FDA claims that whole-body exposures used in the NTP study cannot be related to the local RFR exposures a human receives while using a cell phone. The dismissal of the NTP study results by the FDA is rather peculiar since it was the FDA’s Center for Device and Radiological Health that requested the toxicity and carcinogenicity of RFR in experimental animals (CDRH nomination of RFR) “to provide the basis to assess the risk to human health,” and FDA scientists were fully aware of the exposure methodology that was used in the NTP study long before those studies were begun.

The NTP study was designed to provide accurate organ-specific dosimetry that could be used to quantify risks for any adverse effect that might be identified. Most people who check on the RF emissions from their cell phones learn that the Federal Communication Commission (FCC) requires that local tissue exposures be lower than 1.6 W/kg averaged over any one gram of tissue. In the NTP study, the exposures to the brain of rats were approximately 1.5, 3.0, and 6.0 W/kg – close to the FCC's local exposure limit. For experimental studies in small groups of laboratory animals, these values are unusually close to allowable local tissue exposures in humans and require minimal extrapolation to estimate human cancer risk.

The FDA report complains that the whole-body exposures in the NTP study at 6 W/kg was 75 times higher than the exposure limit for the general population (the lower doses were 38- and 19-times that limit for the general population, but only 8- and 4-times the exposure limit for workers). However, whole body exposures provide little information on organ-specific exposure levels. When an individual holds a cell phone next to their head, the important exposure for consideration of health risk is the local exposure. That is why the NTP study design focused on the local exposure intensities. If the animal studies had used the whole-body exposure limit of 0.08 W/kg, then the exposure to the brain of
exposed animals would have been 20-fold less than the FCC's local exposure limit for the general public, i.e., a useless study for assessing human risk. It is misleading for the FDA document to ignore the local exposure limit of 1.6 W/kg and its importance for assessing organ-specific cancer risk.

The FDA document criticizes studies that did not perform histopathology evaluations blinded to the dose group, including the NTP study. However, as was pointed out previously[1], the final diagnosis of lesions in the NTP study was done by a group of pathologists who did not know whether the slides they were examining came from an exposed or an unexposed animal. In addition, for anyone questioning the diagnosis of any tissue in this study, all of the slides from the NTP studies are available for examination at the NTP archives.

The FDA document also suggests without evidence that the carcinogenic effects in rats exposed to 6 W/kg were due to the loss of their ability to maintain their body temperatures during the exposures. However, measured body temperatures were within 1 ^{o}C of their normal body temperature, there were no differences in body weights between exposed and sham control rats in the 2-year study, there was no indication of tissue damage in the 28-day study, and there were no exposure-related clinical observations in the 2-year study (NTP TR-595). Thus, it is clear that animals tolerated the exposure levels used in the NTP study. The peer reviewers of the NTP studies were fully aware of all issues raised in the FDA document, yet still concluded that the results of those studies showed clear evidence of carcinogenic activity. FDA scientists had the opportunity to offer criticisms of the NTP study prior to and during the 3-day peer-review, but did not. Did the FDA somehow have an epiphany regarding the human relevance of the NTP cancer data or was there some other factor influencing their decision to dismiss those results?

Lastly, the FDA document misstates the results of the genetic toxicology tests in animals from the NTP study. For example, the FDA document claims there were “no statistically significant increases in DNA damage in female rats or either mouse sex” and the increases in DNA damage in male rats “was not statistically significant,” when in fact there were significant increases and significant trends in DNA damage in the frontal cortex of male mice exposed to GSM or CDMA modulated RFR and in the frontal cortex and hippocampus of male rats exposed to CDMA (NTP TR-595).

The FDA document also claims there is a “lack of biological mechanistic plausibility,” while eight *in vivo* studies cited in that document provided evidence of increased oxidative stress associated with exposure to RFR and 15 studies provided evidence of genotoxicity. In addition, many relevant *in vivo* studies showing evidence of oxidative stress were not reported in the FDA document and there are many *in vitro* studies that have found oxidative stress associated with exposure to RFR[2]. A true risk analysis should consider both *in vivo* and *in vitro* studies when ascertaining biological mechanistic plausibility. A characteristic of many human carcinogens is the induction of oxidative stress that can subsequently lead to mutations, chromosomal translocations, and genetic instability.[3] Thus, there does exist a biologically plausible mechanism for the induction or progression of tumors associated with exposure to RFR. For studies that did not show evidence of carcinogenicity or genotoxicity, the FDA document did not comment on whether or not those studies were adequately designed with respect to animal group size, exposure levels and duration of exposure.

Regarding human studies, the FDA document cites the study by Little (2012) in which it was reported that glioma trends in the US between 1997 and 2008 have remained relatively constant, but omitted the study by Philips et al. (2018)[4] that reported a doubling in incidence of glioblastoma (frontal and temporal lobes) in England between 1995 and 2015. The latter study was published in June 2018, which is within the timeframe (August 2018) for epidemiological studies included in the FDA document.

The FDA document identified several human studies that reported risks of glioma, acoustic neuroma, and other tumor types that were increased among cell phone users. In each case, the document focused on limitations in those studies to raise doubt about their reliability for assessing cancer risk. Two limitations specified for most case-control studies included selection and recall bias. However, the FDA document neglected to discuss the impact of the study by Momoli et al.(2017),[5] which re analyzed the Canadian data that was included in the Interphone study and showed that there was no effect on the risk of glioma after adjustments were made for selection and recall biases; the odds ratios (OR) for glioma were significantly increased when comparing the highest quartile of use to those who were not regular users whether or not adjustments were made: OR = 2.0, 95% confidence interval 1.2– 2.4 without adjustment; OR = 2.2 95% confidence interval 1.3–4.1 with adjustments. Evidently, selection and recall biases do not explain the elevated brain cancer risks associated with use of cell phones in that study.

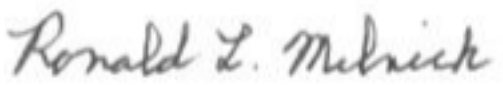
Thus, while there are reliable animal studies, mechanistic studies, and animal studies showing increased cancer risks associated with exposure to cell phone RFR, the FDA document dismisses nearly the entirety of those studies to enable the agency to conclude that there is insufficient evidence to support a causal association between RFR exposure and tumorigenesis. According to the FDA, animal studies are not useful for studying potential effects in humans (though animal studies are used in drug development) and the human studies "were subject to flaws and inaccuracies." Yet, every known human carcinogen is carcinogenic in animals when adequately tested. Public health agencies including the NTP, US EPA, IARC, and the FDA have a long tradition of relying on the relevance of rodent toxicology/carcinogenicity studies to identify hazardous agents and assess human health risks in order to implement public health protective policies. The statement in the FDA report that "if any risk does exist, it is extremely low" is very misleading since the FDA has not performed a quantitative risk assessment on any of the available data sets and, because of the widespread use of cell phones in the US and world-wide, even a small increase in cancer risk would have a serious public health impact.

Based on the FDA review, which is not a risk analysis as stated in the document, the message for the general public appears to be that precautionary measures for use of cell phones are not necessary in spite of the fact that numerous studies have provided compelling evidence of increased cancer risk associated with exposure to cell phone RFR. This is an irresponsible message for a government agency that claims its mission is to protect consumers and promote public health.

The statement on the FDA website (https://www.fda.gov/radiation-emitting-products/cell-phones/do cell-phones-pose-health-hazard) that there is a "scientific consensus on cell phone safety" is totally wrong and should be removed since there is no scientific consensus supporting this claim. In contrast, numerous experts in the field have reported evidence that current levels of cell phone radiation can be harmful to human health.

In conclusion, the FDA document has serious flaws and inaccuracies, as well as omissions of relevant data. Hence, in consideration of public health, it is important that FDA immediately retract their review on radiofrequency radiation and cancer.

Sincerely,



Ronald L. Melnick, Ph.D.
Retired toxicologist NTP, NIEHS

1 Melnick RL (2019). Commentary on the utility of the National Toxicology Program study on cell phone radiofrequency radiation data for assessing human health risks despite unfounded criticisms aimed at

minimizing the findings of adverse health effects. *Environ Res.* 168:1-6.

[2] Yakymenko I, Tsybulin O, Sidorik E, et al. (2016). Oxidative mechanisms of biological activity of low-intensity radiofrequency radiation. *Electromagn Biol* Med 35: 186-202.

[3] Smith MT, Guyton KZ, Gibbons CF, et al. (2016). Key characteristics of carcinogens as a basis for organizing data on mechanisms of carcinogenesis. *Environ Health Perspect*. 124:713-721.

[4] Philips A, Henshaw DL, Lamburn G, O'Carroll MJ. (2018). Brain tumours: rise in glioblastoma multiforme incidence in England 1995-2015 suggests an adverse environmental or lifestyle factor. *J Environ Public Health*. Article ID 7910754, [5] Momoli F, Siemiatycki J, McBride ML, et al. (2017). Probabilistic multiple-bias modeling applied to the Canadian data from the Interphone study of mobile phone use and risk of glioma, meningioma, acoustic neuroma, and parotid gland tumors. *Am J Epidemol*. 186:885-893.

FDA Misrepresentation #3: The FDA has fully evaluated specific non-cancer effects such as oxidative stress, impacts to reproduction and electromagnetic sensitivity.

Fact: The FDA has misrepresented that they have adequately reviewed specific non cancer health endpoints such as oxidative stress and damage to reproduction- but has never publicly released any scientific report documenting the FDA systematically reviewed issues. Despite highlighting the issue of electromagnetic sensitivity on their website, the FDA has shown no science based reports. Although the FDA has been sent several studies and published reviews on this issue indicating harmful effects, the FDA has taken no action.

Sections

1. Documentation that the FDA misrepresents that the FDA has evaluated oxidative stress and made a determination of no effect.
2. Documentation that the FDA misrepresents that they evaluated impacts to reproduction and made a determination of no effect.
3. Documentation that the FDA misrepresents that they evaluated electromagnetic sensitivity and they made a science based determination that people's claims "are not the result of radio frequency exposures."

Documentation that the FDA misrepresents that they evaluated oxidative stress and made a determination of no effect.

In June 13, 2017 email correspondence with EHT's then Executive Director Theodora Scarato (where the FDA repeatedly referred to the "totality" of the science), Scarato asked the FDA's Daniel Kassidy about a 2015 published review (Oxidative mechanisms of biological activity of low-intensity radiofrequency radiation[38]) that found the majority of reviewed studies found oxidative stress (page 33 of FDA/Scarato Correspondence[39]). In response, FDA's Kassiday cited the 2011 monograph that, in fact, did find evidence of oxidative stress (and was notably now more than 7 years outdated) and stated, "We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar e*lectronic products) and adverse health effects."* When Scarato responded with a follow up question of "*How do you substantiate such a statement?*" Kassiday replied, *"From the totality of the scientific literature available and expert opinions."*

However, FDA's Kassiday did not send any reports or evaluations, nor evidence of ongoing FDA monitoring regarding the issue of oxidative stress. Notably, oxidative stress was not in the scope of the 2020 FDA Literature Review.

Documentation that the FDA misrepresents that they evaluated impacts to reproduction and made a determination of no effect.

The June 2017 email correspondence between Scarato and FDA's Kassiday also included a conversation about impacts to sperm, ovaries and fertility. Scarato sent several studies and referenced several papers on EHT's website. The FDA's Kassiday replied that they "*looked at the papers you identified. Those studies suffer from many confounding factors that significantly limit or eliminate their impact. There is insufficient evidence available to establish adverse health effects, including when these studies are taken into account.*" When Scarato asked, *"On what grounds?"* The FDA stated that *"all these studies are insufficient*" then listed, without any scientific references, a short general list of factors why studies might not be relevant and concluded: *"Based on the individual papers and analysis by expert review panels we conclude that the current RF exposure limits adequately protect the public health. This includes reproductive health."*

Note: Scarato also sent extensive scientific citations[40] to the FDA on impacts to reproduction September 21, 2014 in advance of an in-person meeting as well as in several other emails over the years.

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[38] Yakymenko, Igor, et al. "Oxidative Mechanisms of Biological Activity of Low-Intensity Radiofrequency Radiation." *Electromagnetic Biology and Medicine*, vol. 35, no. 2, 2016, pp. 186–202. *PubMed*.

[39] "Email from Theodora Scarato to Abiy Desta regarding : Difference of opinion on the scientific evidence the FDA relies upon to regulate radiofrequency energy emitting products such as cell phones." (November 17, 2017) https://ehtrust.org/wp-content/uploads/FDA-communications-Scarato-PDF-2019.pdf.

[40] "Email from Theodora Scarato to FDA with extensive Scientific Citation." (September 21, 2014) https://ehtrust.org/wp-content/uploads/FDA-communications-Scarato-PDF-2019.pdf.

Notably, numerous published reviews on reproduction have concluded harmful effects from RFR to reproductive endpoints. For example, Maluin et al. 2021[41] systematically reviewed the literature on the effects to male reproductive hormones in experimental animals and humans found that RFR emitted by mobile phones and Wi-Fi devices can cause testosterone reduction. The effects appeared to be related to the duration of mobile phone use and the authors recommend limiting wireless device use.

Documentation that the FDA misrepresents that they evaluated electromagnetic sensitivity and the made a science based determination that people's claims "are not the result of radio frequency exposures."

The FDA misrepresents on their website and in their letters that they evaluated the literature electromagnetic sensitivity and made a determination that people's claims of symptoms such as "are not the result of radio frequency exposures." However the FDA has not made public any report reflecting FDA's systematic review of the science on this issue.

FDA Website page on Electromagnetic Hypersensitivity

The FDA has a section on its website page "Scientific Evidence for Cell Phone Safety"[42] entitled "Electromagnetic Hypersensitivity: Idiopathic Environmental Intolerance to Electromagnetic Fields" that states:

> "To date, the scientific evidence indicates symptoms experienced by people who self-identify as having electromagnetic hypersensitivity occur when the individual believes they are being exposed to radio frequency energy. Based on the available scientific evidence, their very real symptoms are not the result of radio frequency exposures."

FDA Website Information on Electromagnetic Hypersensitivity Links to Outdated Information and is Not a Science Based FDA Review of the Issue

Despite the FDA's verbiage of "to date" scientific research, the only evidence that is referenced on the FDA website in the section on "Electromagnetic Hypersensitivity is a 16 year old online statement[43] clearly headlined as "December 2005" with only 6 citations- half are decades old. Three of the six citations are from the late 1990s and the other three are from 2005 and 2004. The statement linked to is by the EMF Project of the WHO which has not *completed a systematic review of the recent research on this issue.*

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[41] *Frontiers | Effect of Radiation Emitted by Wireless Devices on Male Reproductive Hormones: A Systematic Review | Physiology*. https://www.frontiersin.org/articles/10.3389/fphys.2021.732420/full. Accessed 30 Nov. 2021.
[42] "Scientific evidence for cell phone safety." U.S. Food and Drug Administration. (2020) https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety.
[43] "Electromagnetic hypersensitivity." World Health Organization. (December 2005) https://www.who.int/teams/environment-climate-change-and-health/radiation-and-health/non-ionizing/el-hsensitivity

FDA's Letter to Physicians for Safe Technology Regarding Electromagnetic Hypersensitivity

In a May 23, 2019 FDA Letter to Physicians for Safe Technology Dr. Cindy Russell and Dr. Beatrice Golomb**,** the FDA states that they have monitored the literature on electrical sensitivity and have reviewed reports "from individuals that attribute their symptoms to RF exposure from microwave communication, data transmittal and measurement protocols (e.g., cell phones Wi-Fi routers, smart meters etc.)." and these reports "have not provided information that supports reported RF exposure as causing the adverse health effects and "the research on idiopathic environmental intolerance attributed to electromagnetic fields does not support a finding that EMF exposure is the cause of the symptoms…" The letter then lists a series of references entitled "List of Selected References FDA used as Benchmarks" which mostly references other governments reports and as well as reports by other agencies such as ICNIRP.

If the FDA is utilizing selected government agency conclusions of agencies of Sweden, Netherlands, Canada, England, New Zealand as their own, FDA's decision should be publicly stated along with the FDA methodology for choosing these specific reports. There are medical organizations and other governments that are asserting a different conclusion and recommendations yet the FDA is not choosing to reference them. Furthermore, some of the very countries referenced by the FDA have RF limits and recommendations more stringent than the US (such as Canada) or policies that limit cell towers near schools (such as New Zealand[44]) or reports that recommend reducing cell phone and wireless radiation to children and in schools (such as the European Parliament's Resolution[45] and 2021 Health Impact of 5G Study[46]). Is the FDA simply allowed to cherry pick which reports to use as benchmarks?

The bottom line is that although the FDA asserts that it has reviewed the issue, the FDA has shown no FDA reports or up to date research citations regarding the issue of electromagnetic hypersensitivity or people presenting with illness after RFR exposure. The FDA does not clarify its level of review for this issue and nor for the reports of harm from devices sent to the FDA. The FDA does not clarify how it decides on which governmental reports it embraces as "benchmarks."

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[44] "Cellphone towers on school sites." Ministry of Education in New Zealand. (March 30, 2021). https://www.education.govt.nz/school/property-and-transport/school-facilities/cellphone-towers/ .
[45] "*PACE - Resolution 1815 (2011) - The Potential Dangers of Electromagnetic Fields and Their Effect on the Environment*. http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=17994&. Accessed 30 Nov. 2021.
[46] "Health Impact of 5G Study." EPRS | European Parliamentary Research Service. (July 2021) https://www.europarl.europa.eu/RegData/etudes/STUD/2021/690012/EPRS_STU(2021)690012_EN.pdf.

FDA Misrepresentation #4: The FDA states "the majority of studies" do not show an association between cell phones and health problems.

Fact: The FDA has stated "the majority of studies" do not show an association between cell phones and health problems even though the FDA has not publicly released any report or research list that looked at *all the studies* on cell phones and health issues (cancer and non cancer) in order to make this numerical determination.

- Examples of FDA's misrepresentation regarding its calculation regarding the "majority of studies."
- Documentation that FDA's statements regarding this calculation is unsubstantiated.

Examples of FDA's misrepresentation regarding the "majority of studies"

In the March 2019 FDA letter to Dr. Melnick, Dr. Shuren states:

> *"The majority of studies published have failed to show an association between exposure to radiofrequency from a cell phone and health problems."*
> "*The majority of scientific studies conducted to date have not linked RF energy from using cell phones with any health problems.*"

Documentation that FDA's statements regarding its calculation that the "majority of studies" find no association is unsubstantiated.

1. The FDA has publicly released any report or research list that looked at all the studies on cell phones and health issues (cancer and non cancer) in order to make this numerical determination. Until the FDA publicly releases a report that identifies and evaluates research studies (on all health endpoints) and then mathematically determines if the majority of these studies show harm, the FDA's statement that the "majority of studies do not show an association with health effects" lacks any documented factual basis.

2. Several evaluations of the data have shown that in fact, the majority of studies show effects.
   For example, the Lancet Planetary Health, a highly respected journal, published an article[47] that documents an evaluation on non-ionizing radiation that found the majority of studies show an effect.

[47]Bandara, Priyanka, and David O. Carpenter. "Planetary Electromagnetic Pollution: It Is Time to Assess Its Impact." *The Lancet Planetary Health*, vol. 2, no. 12, Dec. 2018, pp. e512–14. *ScienceDirect*.

> "A recent evaluation of 2,266 studies (including in-vitro and in-vivo studies in human, animal, and plant experimental systems and population studies) found that most studies (n=1546, 68·2%) have demonstrated significant biological or health effects associated with exposure to anthropogenic electromagnetic fields. We have published our preliminary data on radiofrequency electromagnetic radiation, which shows that 89% (216 of 242) of experimental studies that investigated oxidative stress endpoints showed significant effects. This weight of scientific evidence refutes the prominent claim that the deployment of wireless technologies poses no health risks at the currently permitted non-thermal radiofrequency exposure levels."

> The Harvard Press Book by Norm Alster, "Captured Agency: How the Federal Communications Commission is Dominated by the Industries it Presumably Regulates" documents[48]
>
> *"But Dr. Lai found that just over half—actually 56%—of 326 studies identified biological effects. And the results were far more striking when Dr. Lai divided the studies between those that were industry-funded and those that were independently funded. Industry-funded research identified biological effects in just 28% of studies. But fully 67% of non-industry funded studies found biological effects."*

In 2020, Henry Lai PhD updated his reports on published studies finding effects from RFR and non ionizing radiation and posted an analysis as well as all the abstracts[49] on the Bioinitiative Report including the following calculations:

- Neurological RFR studies report effects in 73 % of studies on RF radiation -- or 244 of 336 studies. (Bioinitiative 2020[50]).
- Genetic effect studies report effects in 65 % of studies on RF radiation -- or 224 of 346 studies (Bioinitiative 2020[51]).

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[48] "Harvard Press Book on Telecom Industry Influence To The US FCC - Captured Agency by Norm Alster." *Environmental Health Trust*. Accessed 30 Nov. 2021

[49] The BioInitiative Report and Abstracts.(2012) https://bioinitiative.org/updated-research-summaries/.

[50] Literature on Neurological Effects of Radiofrequency Radiation (2007-2020). https://bioinitiative.org/wp-content/uploads/2020/09/6-RFR-Neurological-Effects-Abstracts-2020.pdf

[51] Literature on Genetic Effects of Non-Ionizing Electromagnetic Fields. The Bioinitiative Report (September 11, 2020). Current to August 29, 2020 https://bioinitiative.org/wp-content/uploads/2020/09/Genetic-Effects-of-Non-Ionizing-EMF-Abstracts-2020-2020.pdf.

- Free Radical (Oxidative Damage) effect studies report effects in 91 % of studies on RF radiation -- or 240 of 261 studies (Bioinitiative 2020[52]).
- RFR Comet Assay effect studies report effects in 65 % of studies on RF radiation -- or 78 of 125 studies (Bioinitiative 2020[53]).

FDA Misrepresentation #5: The FDA states that RFR studies which find biological effects have not been replicated.

Fact: This statement is non factual as biological effects have been replicated. In fact, the FDA's own literature review contains replicated research indicating RFR is a tumor promoter. False general statements like this one on the FDA's public website only serve to downplay the health issue to the American public and government. While RFR research is complex and numerous studies suffer from critical limitations, exposure issues and confounding factors, the fact is that numerous systematic reviews have repeatedly found the same types of biological effects and several studies have been replicated.

Sections

- Example of FDA's erroneous statements asserting that "studies have not been replicated."
- Examples of studies on RFR that replicate biological effects invalidating the FDA's unsubstantiated claim.

Example of FDA's statements asserting that "studies have not been replicated."

FDA's website page Scientific Evidence for Cell Phone Safety inaccurately states:

> "Although some researchers have reported adverse biological changes associated with RF energy, these studies have not been replicated."
>
> This one sentence on the widely read FDA website is used nationwide to downplay studies showing harm.

[52] RFR Free Radical (Oxidative Damage) Studies. The Bioinitiative Report (September 1, 2020). https://bioinitiative.org/wp-content/uploads/2020/09/3-RFR-Free-Radical-Oxidative-Damage-Abstracts-2020.pdf.
[53] Percent Comparison Showing Effect vs No Effect by Comet Assay Studies 2020. The Bioinitiative Report (September 11, 2020). https://bioinitiative.org/wp-content/uploads/2020/09/10.-Comet-Assay-Studies-Percent-Comparison-2020.pdf.

Examples of studies on RFR that replicate biological effects invalidating the FDA's claim.

Biological changes from non ionizing radiation are well recognized and have been replicated. In fact, a critical replication study (Lerchl 2015[54]) is in the FDA's 2020 literature review.

The FDA's use of the word "replicate" on a website for the general public communicates the false illusion that *"even if one study found a problem, no other studies found the same problem."*

In science, researchers look for consistency and corroboration. Every study has limitations and RFR research is especially complex compared to other types of environmental exposures. When a study finds a harmful effect, scientists do follow up studies that address the limitations of the earlier studies to see if the finding is replicated. When it comes to RFR, numerous studies find adverse effects corroborating findings from earlier studies.

As described below, RFR exposure studies have indeed replicated biological effects and numerous studies show consistency in regards to various health endpoints.

The FDA is erroneously dismissing this research and inaccurately characterizes the state of science on its public webpage.

1. The FDA's own 2020 Literature Review contained an important Jacobs University study[55] which found a tumor promotion effect- elevated lymphoma and significantly higher numbers of tumors in the lungs and livers in animals exposed to both RF and a known carcinogen. This study was designed to replicate previous research published in the International Journal of Radiation Biology (Tillman et al., 2010[56]). The authors state:

   > *"Tumor-promoting effects of RF-EMF exposed mice have been reported in 2010. We have replicated the study with higher numbers of mice per group. We could fully confirm the previous results, thus the effects are reproducible.*

2. Replicated research finds behavioral problems associated with cell phone use (prenatally and postnatally) as exemplified by Divan et al. 2012[57] which replicated Divan et al. 2008[58] finding behavioral issues in children.
   The replication study Divan et al 2012 concludes in the abstract:

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[54] Lerchl, Alexander, et al. "Tumor Promotion by Exposure to Radiofrequency Electromagnetic Fields below Exposure Limits for Humans." *Biochemical and Biophysical Research Communications*, vol. 459, no. 4, Apr. 2015, pp. 585–90. *ScienceDirect*.
[55] Lerchl, A., et al. "Tumor promotion by exposure to radiofrequency electromagnetic fields below exposure limits for humans." *Biochemical and Biophysical Research Communications*. (March 6, 2015).
[56] Tillmann, T., et al. "Indication of co carcinogenic potential of chronic UMTS-modulated radiofrequency exposure in an ethylnitrosourea mouse model." *International journal of radiation biology*, (2010) *86*(7), 529–541.
[57] Divan, H. A., et al. "Cell phone use and behavioural problems in young children." *Journal of epidemiology and community health*, (2012) *66*(6), 524–529.
[58] Divan, H. A., et al. "Prenatal and postnatal exposure to cell phone use and behavioral problems in children." *Epidemiology* (Cambridge, Mass.), (2009)*19*(4), 523–529.

"Conclusions: The findings of the previous publication were replicated in this separate group of participants demonstrating that cell phone use was associated with behavioural problems at age 7 years in children, and this association was not limited to early users of the technology."

3. A study out of the Swiss Tropical and Public Health Institute (Foerster 2018)[59] found damage to memory in teenagers who use cell phones to their head. This study was a "follow up" to Schoeni et al 2015[60] with twice the same size, better information on exposure and better methods for confounding factors. The July 2018 press release[61] states:

   "The study to be published on 19 July 2018 found that cumulative RF-EMF brain exposure from mobile phone use over one year may have a negative effect on the development of figural memory performance in adolescents, confirming prior results published in 2015."

4. Research consistently finds an effect on brain activity measured by electroencephalography. This effect is well recognized- even by groups that dismiss health effects. It is a biological effect and considered replicated. Research that consistently finds alterations in the electroencephalogram (EEG) includes (Loughran et al. 2012[62]; Lustenberger et al. 2013[63]; Regel et al. 2007[64]; Schmid et al. 2011[65]). A 2019 review (Wallace and Selmaoui 2019[66]) found "the most consistent results concerned the effect of radiofrequency on the waking EEG.Indeed, exposure to the radiofrequency signals was observed to modify the waking spontaneous EEG, especially in the alpha band frequency. More significantly, as shown in Figure 1, the majority of all selected studies for this review (80%) found a modification of the spontaneous EEG related to exposures to 2G system or more recent ones, as 3G and 4G, especially in the range of the alpha band."

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[59] Milena Foerster, A., et al. "A Prospective Cohort Study of Adolescents' Memory Performance and Individual Brain Dose of Microwave Radiation from Wireless Communication. Environmental Health Perspectives" (2018) 126:7 CID: 077007.
[60] Schoeni, A., Roser, K., & Röösli, M. "Memory performance, wireless communication and exposure to radiofrequency electromagnetic fields: A prospective cohort study in adolescents." *Environment International.* (October 30, 2015).
[61] Swisstph. (n.d.). "Mobile phone radiation may affect memory performance in adolescents." *EurekAlert!* (July 2018).
[62] Loughran, Sarah P., et al. "Individual Differences in the Effects of Mobile Phone Exposure on Human Sleep: Rethinking the Problem." *Bioelectromagnetics*, vol. 33, no. 1, 2012, pp. 86–93. *Wiley Online Library*.
[63] Lustenberger, Caroline, et al. "Stimulation of the Brain With Radiofrequency Electromagnetic Field Pulses Affects Sleep-Dependent Performance Improvement." *Brain Stimulation: Basic, Translational, and Clinical Research in Neuromodulation*, vol. 6, no. 5, Elsevier, Sept. 2013, pp. 805–11. *www.brainstimjrnl.com*.
[64] Regel, Sabine J., et al. "Pulsed Radio-Frequency Electromagnetic Fields: Dose-Dependent Effects on Sleep, the Sleep EEG and Cognitive Performance." *Journal of Sleep Research*, vol. 16, no. 3, 2007, pp. 253–58. *Wiley Online Library*.
[65] Schmid, Marc R., et al. "Sleep EEG Alterations: Effects of Different Pulse-Modulated Radio Frequency Electromagnetic Fields." *Journal of Sleep Research*, vol. 21, no. 1, 2012, pp. 50–58. *Wiley Online Library*.
[66] Wallace, Jasmina, and Brahim Selmaoui. "Effect of Mobile Phone Radiofrequency Signal on the Alpha Rhythm of Human Waking EEG: A Review." *Environmental Research*, vol. 175, Aug. 2019, pp. 274–86. *ScienceDirect*.

5. Research looking at reproductive endpoints has found adverse effects. Negi and Singh 2021[67] state in their review, " Cell phone radiation harms male fertility by affecting the different parameters like sperm motility, sperm count, sperm morphology, semen concentration, morphometric abnormalities, increased oxidative stress along with some hormonal changes." A systematic review of Wi-Fi on male reproduction (Jaffar 2019[68]) states, "Sperm count, motility and DNA integrity were the most affected parameters when exposed to RF-EMR emitted by Wi-Fi transmitters" and concludes, "exposure towards 2.45 GHz RF-EMR emitted by Wi-Fi transmitter is hazardous on the male reproductive system." Houston et al.2016[69] states "Among a total of 27 studies investigating the effects of RF-EMR on the male reproductive system, negative consequences of exposure were reported in 21.

6. Regarding cancer, recent studies in animals corroborate the studies in humans who use cell phones up to their head. Independent studies in people have found that long-term use of cell phones increases tumor risk (Interphone Study Group. 2010[70]; Hardell et al. 2013[71]; Coureau et a. 2014[72]) and the same tumor types have also been found in the large scale animal studies of the NTP and Ramazzini Institute (NTP, 2018[73], Falcioni et al., 2018[74]). As of 2020, several expert independent scientists have published their evaluation that the scientific evidence has increased and radiofrequency radiation should be classified as proven human carcinogen (Belpomme et al., 2018[75], Miller et al., 2018[76],

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[67] Negi, Pooja, and Rajeev Singh. "Association between Reproductive Health and Nonionizing Radiation Exposure." *Electromagnetic Biology and Medicine*, vol. 40, no. 1, Taylor & Francis, Jan. 2021, pp. 92–102. *Taylor and Francis+NEJM*, https://doi.org/10.1080/15368378.2021.1874973.

[68] Jaffar, Farah Hanan Fathihah, et al. "Adverse Effects of Wi-Fi Radiation on Male Reproductive System: A Systematic Review." *The Tohoku Journal of Experimental Medicine*, vol. 248, no. 3, July 2019, pp. 169–79. *PubMed*, https://doi.org/10.1620/tjem.248.169.

[69]

[70] The INTERPHONE Study Group. "Brain Tumour Risk in Relation to Mobile Telephone Use: Results of the INTERPHONE International Case–Control Study." *International Journal of Epidemiology*, vol. 39, no. 3, June 2010, pp. 675–94. *Silverchair*, https://doi.org/10.1093/ije/dyq079.

[71] Hardell, L., Carlberg, M., & Hansson Mild, K. "Use of mobile phones and cordless phones is associated with increased risk for glioma and acoustic neuroma." *Pathophysiology : The Official Journal of the International Society for Pathophysiology*, (2013). *20*(2), 85–110. https://doi.org/10.1016/j.pathophys.2012.11.001.

[72] Coureau, G.,et al. "Mobile phone use and brain tumours in the CERENAT case-control study. Occupational & Environmental Medicine." (July 1, 2014). https://oem.bmj.com/content/71/7/514.

[73] "Testing Status of Cell Phone Radiation." *National Toxicology Program.* https://ntp.niehs.nih.gov/whatwestudy/testpgm/status/ts-08013.html?utm_source=direct&utm_medium=prod&utm_campaign=ntpgolinks&utm_term=ts-08013.

[74] Falcioni, L., et al. "Report of Final Results Regarding Brain and Heart Tumors in Sprague-Dawley Rats Exposed from Prenatal Life until Natural Death to Mobile Phone Radiofrequency Field Representative of a 1.8 GHz GSM Base Station Environmental Emission." *Environmental Research*, vol. 165, Aug. 2018, pp. 496–503. *ScienceDirect*, https://doi.org/10.1016/j.envres.2018.01.037.

[75] Belpomme, Dominique, et al. "Thermal and Non-Thermal Health Effects of Low Intensity Non-Ionizing Radiation: An International Perspective." *Environmental Pollution (Barking, Essex: 1987)*, vol. 242, no. Pt A, Nov. 2018, pp. 643–58. *PubMed*, https://doi.org/10.1016/j.envpol.2018.07.019.

[76] Miller, Anthony B., et al. "Cancer Epidemiology Update, Following the 2011 IARC Evaluation of Radiofrequency Electromagnetic Fields (Monograph 102)." *Environmental Research*, vol. 167, Nov. 2018, pp. 673–83. *ScienceDirect*, https://doi.org/10.1016/j.envres.2018.06.043.

Carlberg and Hardell 2017[77], Hardell and Carlberg 2019[78]). The European Parliament's European Parliamentary Research Service Study "Health Impact of 5G" concludes the frequencies of 450 to 6 000 MHz " are probably carcinogenic for humans, in particular related to gliomas and acoustic neuromas." Choi 2020[79] concludes, "This comprehensive meta-analysis of case-control studies found evidence that linked cellular phone use to increased tumor risk."
Hardell and Carlberg (2019) conclude:

> *"There is clear evidence that RF radiation causes cancer/tumor at multiple sites, primarily in the brain (glioma) and head (acoustic neuroma). There is also evidence of an increased risk of developing other tumor types. The results are similar in both the NTP studies (19,20) and the Ramazzini Institute ndings (34). Based on the IARC preamble to the monographs, RF radiation should be classified as Group 1: The agent is carcinogenic to humans."*

FDA Misrepresentation #6: The FDA presents inaccurate information about the National Toxicology Program (NTP) animal study findings in order to dismiss the significance of the cancer findings.

Fact: The FDA has presented inaccurate and highly misleading information about the NTP study findings[80] to the public, elected officials and federal agencies. The FDA omits that the NTP study is significant because effects were found at non thermal levels, indicating the basis for FCC limits is faulty.

As Dr. Melnick writes in "There's a clear cell phone-cancer link, but FDA is downplaying it":
"The NTP studies were conducted to test the widely-held assumption that cell phone radiofrequency radiation could not cause cancers or other adverse health effects (other than by tissue heating) because this type of radiation (non-ionizing) did not have sufficient energy to break chemical bonds. The NTP findings that cell phone radiation caused cancers in the heart and brain, DNA damage in brain cells, heart muscle disease and reduced birth weights clearly

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[77] Carlberg, Michael, and Lennart Hardell. "Evaluation of Mobile Phone and Cordless Phone Use and Glioma Risk Using the Bradford Hill Viewpoints from 1965 on Association or Causation." *BioMed Research International*, vol. 2017, Hindawi, Mar. 2017, p. e9218486. *www.hindawi.com*, https://doi.org/10.1155/2017/9218486.
[78] Hardell, Lennart, and Michael Carlberg. "Comments on the US National Toxicology Program Technical Reports on Toxicology and Carcinogenesis Study in Rats Exposed to Whole-Body Radiofrequency Radiation at 900 MHz and in Mice Exposed to Whole-Body Radiofrequency Radiation at 1,900 MHz." *International Journal of Oncology*, vol. 54, no. 1, Jan. 2019, pp. 111–27. *PubMed*, https://doi.org/10.3892/ijo.2018.4606.
[79] Choi, Yoon-Jung, et al. "Cellular Phone Use and Risk of Tumors: Systematic Review and Meta-Analysis." *International Journal of Environmental Research and Public Health*, vol. 17, no. 21, Nov. 2020, p. 8079. *PubMed Central*, https://doi.org/10.3390/ijerph17218079.
[80] "Testing Status of Cell Phone Radiation." *National Toxicology Program.* https://ntp.niehs.nih.gov/whatwestudy/testpgm/status/ts-08013.html?utm_source=direct&utm_medium=prod&utm_campaign=ntpgolinks&utm_term=ts-08013.

demonstrate that the assumption that non-ionizing radiation cannot cause cancer or other health effects is wrong."

The FDA also posts inaccurate statements and has not corrected their statements, despite being provided factual information and a science-based request for corrections by NIH scientists and experts. Furthermore, the FDA mischaracterizes the study by omitting the key findings and putting forward unfounded criticisms.

The end result of this deception is that the public believes this large-scale animal study has no relevance to human health, elected officials believe the study is irrelevant to policy decisions and the U.S. federal regulations for human exposure are believed to be adequate to protect public health.

- The National Toxicology Program study results indicate the existence of carcinogenic effects at non-heating non thermally relevant RFR levels.
- The FDA's inaccurate statements and mischaracterizations of the NTP study.
- Scientists repeatedly wrote the FDA requesting corrections regarding the FDA's erroneous presentation of the NTP study and received inadequate response.
- The FDA has been fully aware of the design of the NTP study for years and never registered any objections.

The National Toxicology Program study results indicate the existence of carcinogenic effects at non-heating non-thermally relevant RFR levels.

In 1999, the FDA nominated the NTP to initiate large-scale animal studies in order to gain an understanding of the long-term effects of exposure to RFR. The study was designed to test the long held assumption that heating was the only harm from RFR. This *heating (thermal) is the only harm* assumption is what U.S. federal exposure limits are based on. As Dr. Melnick states, "this study was designed to test the (null) hypothesis that cell phone radiation at non-thermal exposure intensities could not cause adverse health effects, and to provide dose-response data for any detected toxic or carcinogenic effects."

Although the animals were carefully exposed to RFR levels that did not substantially elevate their temperature to levels considered thermally relevant, the final 2018 NTP reports reported adverse effects- an association between RFR and malignant schwannomas (schwann cell tumors) of the heart, malignant gliomas of the brain and adrenal gland tumors in male rats. These results, as well as the findings of significantly increased DNA damage (strand breaks) in the brains of exposed rats and mice, reduced pup birth weights when pregnant dams were exposed to GSM- or CDMA-modulated RFR, and the induction of cardiomyopathy of the right ventricle in male and female rats clearly demonstrate increased risks of cancer, DNA and other damage.

The NTP findings are important because, in 2011, the International Agency for the Research on Cancer (IARC) classified radio frequency radiation as a "possible human carcinogen" based largely on increased risks of gliomas and acoustic neuromas (which are Schwann cell tumors on the acoustic nerve) among long term users of cell phones[81]. One of the reasons the IARC decided not to classify RFR as a "probable" or "proven" carcinogen at that time was that there was a lack of experimental animal data that had investigated long term chronic exposure in a highly controlled setting. The fact that the tumors found in the NTP animal study are of the same cell type as tumors found elevated in people who use cell phones for many years strengthens the animal-to-human association.

As with prior animal studies finding such adverse effects concordant with the human data, the next step for the FDA should have been a quantitative risk assessment to *use the animal data* to determine the risk to humans.

However, instead of a quantitative risk assessment, the FDA dismissed the study with unfounded criticisms which were presented in two statements by FDA's Dr. Shuren posted on the FDA website in November and February of 2018, the 2020 Literature Review and FDA's official letters.

The FDA's dismissal of the study contained unfactual and unfounded criticisms.

For example, contrary to the FDA assertion also invoked by the FCC, that the exposures were excessively high, the rodent exposure chambers developed for the NTP relied on state of the art methods that did not induce relevant increases in temperature, and approximated exposures humans can receive in their 70+ year lifetimes.

After the FDA's unfounded criticisms were posted Dr. Melnick, a 28-year NIH scientist who led the design of the NTP study, reviewed each criticism and provided the data explaining how each criticism was unfounded in "Commentary on the utility of the National Toxicology Program study on cell Phone radiofrequency radiation data for assessing human health risks despite unfounded criticisms aimed at minimizing the findings of adverse health effects"[82] published in Environmental Research which concludes, "the expert peer-review panel clearly recognized the validity and biological significance of the adverse health effects produced in the NTP's studies of cell phone RFR. The overall results from the NTP studies indicate that cell phone RFR is potentially carcinogenic to multiple organs of exposed people."

Dr. Melnick published a second article on the unfounded criticisms leveled against the NTP entitled "Regarding ICNIRP'S Evaluation of the National Toxicology Program's Carcinogenicity

[81] International Agency for Research on Cancer (IARC). Non-ionizing radiation, Part II: Radiofrequency electromagnetic fields. IARC Monogr Eval Carcinog Risks Hum. 2011;102(2):1-460. https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono102.pdf.
[82] Melnick, Ronald L. "Commentary on the Utility of the National Toxicology Program Study on Cell Phone Radiofrequency Radiation Data for Assessing Human Health Risks despite Unfounded Criticisms Aimed at Minimizing the Findings of Adverse Health Effects." *Environmental Research*, vol. 168, Jan. 2019, pp. 1–6. *PubMed*, https://doi.org/10.1016/j.envres.2018.09.010.

Studies on Radiofrequency Electromagnetic Fields."[83] Melnicks papers address both ICNIRP and the FDA's criticisms of the study including the issues of design, exposure levels, survival, relevance to humans, statistical power, pathology evaluations and more with data and statistics documenting each criticism is unfounded.

Further, Melnick explains how the NTP study results "clearly demonstrate the induction of proliferative lesions (tumors and hyperplasias in the brain and heart) by RFR in conventional animal models," referencing how the Ramazzini Institute study[84] also reported a significant increase in heart schwannomas in male Sprague-Dawley rats and how the incidence of heart Schwann cell hyperplasia was also increased. Melnick explains how the combined incidence of schwannomas and preneoplastic Schwann cell hyperplasias is highly significant. The RI findings "are consistent with the results from the NTP study and demonstrate that the proliferative effect of modulated RFR in heart Schwann cells is a reproducible finding."

Hardell and Carlberg published a 2019 article "Comments on the US National Toxicology Program technical reports on toxicology and carcinogenesis study in rats exposed to whole-body radiofrequency radiation at 900 MHz and in mice exposed to whole-body radiofrequency radiation at 1,900 MHz" [85]analyzing the NTP and RI data and they conclude that," We conclude that there is clear evidence that RF radiation is a human carcinogen, causing glioma and vestibular schwannoma (acoustic neuroma). There is some evidence of an increased risk of developing thyroid cancer, and clear evidence that RF radiation is a multi-site carcinogen. Based on the Preamble to the IARC Monographs, RF radiation should be classified as carcinogenic to humans, Group 1."

As Dr. Melnick concludes, "Even a small increase in cancer risk could have a serious health impact due to the widespread use of cell phones (~300 million in the US and 5 billion worldwide). In the meantime, precautionary principles should be promoted by health and regulatory agencies, especially for children and pregnant women."

The FDA's inaccurate statements and mischaracterizations of the NTP study

The FDA has made numerous inaccurate statements, misleading statements and omissions regarding the NTP study and its relevance to human health. In this Declaration we will highlight

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[83]Melnick, Ronald. "Regarding ICNIRP'S Evaluation of the National Toxicology Program's Carcinogenicity Studies on Radiofrequency Electromagnetic Fields." *Health Physics*, vol. 118, no. 6, June 2020, pp. 678–82. *journals.lww.com*, https://doi.org/10.1097/HP.0000000000001268.

[84]Falcioni, L., et al. "Report of Final Results Regarding Brain and Heart Tumors in Sprague-Dawley Rats Exposed from Prenatal Life until Natural Death to Mobile Phone Radiofrequency Field Representative of a 1.8 GHz GSM Base Station Environmental Emission." *Environmental Research*, vol. 165, Aug. 2018, pp. 496–503. *ScienceDirect*, https://doi.org/10.1016/j.envres.2018.01.037.

[85]Hardell, Lennart, and Michael Carlberg. "Comments on the US National Toxicology Program Technical Reports on Toxicology and Carcinogenesis Study in Rats Exposed to Whole-Body Radiofrequency Radiation at 900 MHz and in Mice Exposed to Whole-Body Radiofrequency Radiation at 1,900 MHz." *International Journal of Oncology*, vol. 54, no. 1, Jan. 2019, pp. 111–27. *PubMed*, https://doi.org/10.3892/ijo.2018.4606.

only a few key examples. To see the full list please review the scientific letters posted on the EHT website.[86] In short, the FDA's treatment of the NTP is a complete whitewash.

- The FDA does not accurately report the findings of the NTP. First and foremost, the FDA's webpage Scientific Evidence for Cell Phone Safety has "5 Facts About the Rat Study" yet none of these "5 Facts" include the key findings of the studies: "clear evidence" of cancer in male rats and DNA damage. **In fact, nowhere on the entire FDA cell phone website page is it ever stated that the NTP study actually found cancer in male rats.**
- The FDA's "5 Facts" misleadingly presents, *"The study found no health effects on female rats or mice (both male and female) exposed to these extreme conditions that passed a test for statistical significance*", however, the comet assay showed significant increases in DNA damage[87] in the frontal cortex of male mice (both modulations), leukocytes of female mice (CDMA only) and hippocampus of male rats (CDMA only). Further, there was an unusual pattern of cardiomyopathy[88] (damage to heart tissue) in RFR-exposed male and female rats.
- The FDA's "5 Facts" are misleading and inaccurate. The FDA misleadingly states that "Rats received levels of radiation that were up to 75 times higher than the whole-body exposure limit for people", but, as Dr. Ronald Melick points out, the NTP's levels of 1.5 W/kg, 3 W/kg and 6.0 W/kg are the same and only slightly higher than FCC's 1.6 W/kg (general public) and 8 W/kg (occupational exposure) SAR limit for localized exposure—the FCC's limits when a cell phone is held to the head or body. The highest NTP exposure is not even double what the FCC allows to our arms and legs -FCC limit for arms and legs is 4W/kg (general public) and 20W/kg (occupational). The FDA's focus on full-body limits is not in line with the study design. The study was designed to test the hypothesis that heating was the only harm from RFR. **At a minimum, the FDA could at least explain that the NTP exposures are in fact comparable to tissue exposures that a person would receive with a phone to the head or body. Instead the FDA puts forward half-truths and misleading statements that downplay the importance of the findings.**
- The FDA webpage "5 Facts" also states that "Rats received this whole-body radiation for nine hours per day for their entire lives." **Again, the FDA is presenting misleading information.**

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[86] "Scientific Letters from expert physicians, surgeons and scientists call for FDA to retract "biased" anonymous report of cancer impacts of cell phones." (June 5, 2020) https://ehtrust.org/expert-physicians-surgeons-and-scientists-call-for-fda-to-retract-biased-anonymous-report-of-cancer-impacts-of-cell-phones/.

[87] Smith-Roe, Stephanie L., et al. "Evaluation of the Genotoxicity of Cell Phone Radiofrequency Radiation in Male and Female Rats and Mice Following Subchronic Exposure." *Environmental and Molecular Mutagenesis*, vol. 61, no. 2, 2020, pp. 276–90. *Wiley Online Library*, https://doi.org/10.1002/em.22343.

[88] Uche, Uloma Igara, and Olga V. Naidenko. "Development of Health-Based Exposure Limits for Radiofrequency Radiation from Wireless Devices Using a Benchmark Dose Approach." *Environmental Health*, vol. 20, no. 1, July 2021, p. 84. *BioMed Central*, https://doi.org/10.1186/s12940-021-00768-1.

a. First, the rats were sacrificed at two years and did not get a chance to live their "entire lives." (They could have lived longer as rodents can live to around three years.) Importantly, the NTP study found several pre-cancerous lesions called hyperplasia that quite possibly would have been deemed as cancers *had the NTP animal been able to live till natural death,* but as the NTP study did not run that long, data on cancers after two years of exposure simply does not exist.
b. Second, the NTP's genotoxicity studies (whereby a smaller group of rodents were sacrificed very early in the study) sacrificed the animals at 13 to 19 weeks *and they found DNA damage*.
c. Further, in contrast to the NTP, the Ramazzini Institute's large-scale RFR rat study let their rats live until natural death (up to around three years) and found cancerous tumors in the last part of the rats' life—*a time period the NTP did not evaluate*. Of critical importance is the fact that the Ramazzini Institute used RFR exposures much much lower than the NTP and yet found the same tumor types that the NTP found.

- The FDA's wordsmithing downplays the NTP study. As an example of this wordsmithing, the FDA webpage has a section entitled "On this page" that links to the issues covered on the website. The NTP issue is entitled "The FDA's Review of the National Toxicology Program's Studies in High Dose Radio Frequency Radiation"[89] entirely void of the fact that it was a "carcinogenicity" study.
- At the end of the FDA website on the science is a section entitled "Scientific Information About Radio Frequency Exposure" and yet this section omits any link to the actual final reports of the NTP study or any link to the NTP's webpage on their own study.

Letter to members of Congress: In its 2019 letter,[90] the FDA presented similar inaccurate information regarding the NTP to Representative Eshoo and Senator Merkley, stating, *"Furthermore, no effects were seen in mice of either sex or in female rats"* despite the fact that heart damage was found in female rats and DNA damage was found in certain mice and rat groups.

2020 Literature Review: In addition to the website inaccuracies on the NTP, the FDA 2020 Literature Review itself also inaccurately presents the results of the NTP's genotoxicity tests. Dr. Melnick explains:

> *"Lastly, the FDA document misstates the results of the genetic toxicology tests in animals from the NTP study. For example, the FDA document claims there were 'no statistically significant increases in DNA damage in female rats or either mouse sex' and the increases in DNA damage in male rats 'was not statistically significant,' when in fact there were significant increases and significant trends in DNA damage in the frontal cortex of male mice exposed to GSM or CDMA*

[89] Health, Center for Devices and Radiological. "Scientific Evidence for Cell Phone Safety." *FDA*, FDA, Feb. 2020. *www.fda.gov*, https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety.

[90] "FDA letter to Anna Eshoo and Senator Merkley." (September 09, 2019) https://ehtrust.org/wp-content/uploads/FDA-letter-to-Eshoo-re-cell-phone-RF-safety.pdf.

modulated RFR and in the frontal cortex and hippocampus of male rats exposed to CDMA (NTP TR-595).”

Scientists repeatedly wrote the FDA requesting corrections regarding the presentation of the NTP study and received inadequate response.

Dr. Ronald Melnick wrote two letters to the FDA, sent along with additional letters from EHT and other expert scientists, detailing the “major incorrect statements and omissions of relevant data.” These letters were sent on December 7, 2018[91] and on February 27, 2020[92]. The FDA only responded to the first letter of March 14, 2019[93] *without* addressing all of the scientists’ questions; and the FDA did not respond to the second batch of scientists’ letters in 2020 detailing the incorrect information.

In addition to requesting corrections from the FDA, Dr. Ronald Melnick has published two articles [94] [95]debunking the inaccuracies and unfounded criticisms of the NTP study. Further, Dr. Linda Birnbaum, former Director of the National Institute of Environmental Health Sciences and of the National Toxicology Program, sent a Declaration into an Amicus Brief[96] in EHT and Theodora Scarato and petitioners case against the FCC detailing how such criticisms are unfounded and how the NTP study is in fact relevant to human health stating, “Overall, the NTP findings demonstrate the potential for RFR to cause cancer in humans.”

The FDA has been fully aware of the design of the NTP study for years and never registered any objections.

The FDA has been aware of the design of the NTP study for years. Thus the FDA contradicts itself when it rejects the findings based on the design.

The FDA was fully aware of the NTP study design and was repeatedly referenced as working in collaboration with NIH on the study. Yet the FDA then rejected the study based on the design because the cancer was found at such “high” exposure levels. (These criticisms are unfounded as discussed earlier in this section.)

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[91] “Dr. Ronald Melnick’s letter to the FDA.” (December 17, 2018) https://ehtrust.org/wp-content/uploads/Letter-to-FDA-From-Scientists-on-FDA-Rejection-of-NTP-study-and-FCC-Limits-sent-December-17-2.pdf.

[92] “Igor Belyaev, PhD letter to FDA.” https://ehtrust.org/wp-content/uploads/Scientists-Letters-to-FDA.pdf.

[93] “FDA Letter response to Dr. Ronald Melnick et al.” (March 14, 2019) https://ehtrust.org/wp-content/uploads/Dr.-Shuren-Response-Scientists-March-14-2019.pdf

[94]Melnick, Ronald. “Regarding ICNIRP’S Evaluation of the National Toxicology Program’s Carcinogenicity Studies on Radiofrequency Electromagnetic Fields.” *Health Physics*, vol. 118, no. 6, June 2020, pp. 678–82. *journals.lww.com*, https://doi.org/10.1097/HP.0000000000001268.

[95]Melnick, Ronald L. “Commentary on the Utility of the National Toxicology Program Study on Cell Phone Radiofrequency Radiation Data for Assessing Human Health Risks despite Unfounded Criticisms Aimed at Minimizing the Findings of Adverse Health Effects.” *Environmental Research*, vol. 168, Jan. 2019, pp. 1–6. *ScienceDirect*, https://doi.org/10.1016/j.envres.2018.09.010.

[96] Amicus Curiae Joseph Sandri, United States Court of Appeals For the District of Columbia Circuit, USCA Case #20-1025 Document #1855264 Filed: 08/05/2020.
https://ehtrust.org/wp-content/uploads/20-1025-Amicus-Brief-Joe-Sandri.pdf Amicus Joe Sandri

The FDA could have contacted the NTP ***at any point in the process***, especially at the beginning when the NTP study design was in development and presented- however the FDA did not. Examples of critical times when the FDA could have expressed an opinion to NTP and NIH about the study design but did not include:

- After or during the 2009 Congressional hearings on cell phone radiation and health effects where John Bucher Associate Director National Institute of Environmental Health Sciences/National Toxicology Program presented the study design (CSPAN link) .
- During or after the 2009 conference in Washington DC coordinated by EHT and attended by the FCC and FDA with presentations by NIH and the American Cancer Society later followed by the release of a Research Agenda. At this conference NTP scientist Michael Wyde presented the study design (See Wyde Presentation Part 1, See Wyde Presentation Part 2) The FDA was in attendance and spoke as well (See FDA Abiy Desta).
- The 6 times a year radiofrequency interagency workgroup phone meetings where the FDA is listed as a participant.
- When the study was presented at an annual meeting of the Bioelectromagnetics Society prior to the start.
- During the March 26-28, 2018 peer review of the NTP study[97] where the FDA offered no written or in person comments at all.
- At any point over the last decade.

The FDA is rejecting the NTP studies because it was on animals, however in addition to the FDA requesting the NTP do animal studies, the FDA has long advocated for animal research to understand the health issues of cell phone radiation.

A letter from the Food and Drug Administration to the Honorable Edward J. Markey on May 5, 1997 states.

- Chronic (lifetime) animal exposures should be given highest priority.
- Chronic animal exposures should be performed both with and without the application of chemical initiating agents to investigate tumor promotion in addition to tumorigenesis.

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[97] Capstick, Myles H., et al. "A Radio Frequency Radiation Exposure System for Rodents Based on Reverberation Chambers." *IEEE Transactions on Electromagnetic Compatibility*, vol. 59, no. 4, Aug. 2017, pp. 1041–52. *DOI.org (Crossref)*, https://doi.org/10.1109/TEMC.2017.2649885.
- Gong, Yijian, et al. "Life-Time Dosimetric Assessment for Mice and Rats Exposed in Reverberation Chambers for the Two-Year NTP Cancer Bioassay Study on Cell Phone Radiation." *IEEE Transactions on Electromagnetic Compatibility*, vol. 59, no. 6, Dec. 2017, pp. 1798–808. *DOI.org (Crossref)*, https://doi.org/10.1109/TEMC.2017.2665039.
- National Toxicology Program (NTP). *Toxicology and Carcinogenesis Studies of GSM- and CDMA-Modulated Cell Phone Radio Frequency Radiation at 1,900 MHz in B6C3F1/N Mice Exposed via Whole Body Exposure*. National Institute of Environmental Health and Safety, Oct. 2018, p. TR-596. *DOI.org (Crossref)*, https://doi.org/10.22427/NTP-DATA-TR-596.
- National Toxicology Program (NTP). *Toxicology and Carcinogenesis Studies of GSM- and CDMA-Modulated Cell Phone Radio Frequency Radiation at 900 MHz in Hsd:Sprague Dawley SD Rats Exposed via Whole Body Exposure*. National Institute of Environmental Health and Safety, Oct. 2018, p. TR-595. *DOI.org (Crossref)*, https://doi.org/10.22427/NTP-DATA-TR-595.

- Identification of potential risks should include endpoints other than brain cancer (e.g., ocular effects of radiofrequency radiation exposure).

A 1995 GAO report RCED-95-32 Telecommunications: Status of Research on the Safety of Cellular Telephones states:

- "However, controlled laboratory studies on animals and living cells are also needed, according to FDA and the National Science Foundation, to determine if radiation from portable cellular telephones poses a human health risk."

The question the American public and elected officials should be asking is *"Why did the FDA allow the NTP to spend $30 M dollars on an animal study the FDA requested- but was designed to provide no information on human health effects? What information could this animal study provide for understanding human health risks? If the FDA thought the study was poorly designed, why didn't the FDA contact the NTP and NIH scientists to tell them to make adjustments? The NTP clearly showed cancers in specific tissue types in animals at levels that people could receive into their own tissues when using a cell phone in close body/brain contact. The NTP found cancer from non heating exposures. So why is the FDA dismissing this?" However elected officials and the media are unaware of the complexity of the science, unaware of the basis for human exposure limits and unaware of the history of the NTP study and thus are not asking these questions.*

In contrast to the FDA's disagreement with the NTP conclusions, there are numerous examples of how the FDA repeatedly indicated that they supported the design of the $30 M NTP study over the years since the NTP study was first nominated.

On the FDA website on February 3, 2004 the FDA states:

> *"What is FDA doing to find out more about the possible health effects of wireless phone RF?*
> *"FDA is working with the U.S. National Toxicology Program and with groups of investigators around the world to ensure that high priority animal studies are conducted to address important questions about the effects of exposure to radiofrequency energy (RF)."*

For example, the GAO Report 'Telecommunications: Exposure and Testing Requirements for Mobile Phones Should Be Reassessed' which was released on August 7, 2012 states:

> *"According to FDA officials, FDA is conducting one of these National Toxicology Program studies in its National Center for Toxicological Research laboratory. "*
> *For example, FDA officials reported that FDA's National Center for Toxicological Research, with funding provided by NIH as part of the National Toxicology Program, is conducting studies on rat and bovine brain cells to examine whether RF energy emitted from mobile phones is toxic.*

See the January 13, 2004 National Toxicology Program Website that provides study rationale for cell phone radiation by the FDA.

Substances Nominated to the NTP for Study and Testing Recommendations Made by the ICCEC on December 13, 1999

Table 1. -- Substances Recommended for Testing

Substance [CAS Number]	Nominated by	ICCEC Recommendations	Study Rationale; Other information
			available
Radio frequency radiation emissions of wireless communication devices	FDA	-establish interagency program to design studies assessing cancer and non-cancer health effects to fulfill regulatory needs	Widespread consumer and worker exposure; available data is inadequate to properly assess safety

Additional Resources on the NTP
National Toxicology Program Cell Phone Radiation Webpage
EHT webpage on the NTP study with videos from peer review and links to published research

The NTP study was designing using established protocol for risk assessment of carcinogenic and toxic products.

Read "Guidelines for Carcinogen Risk Assessment" pg no 2-16 "Dosing Issues" .

> “Dose selection should be made on the basis of relevant toxicologic information from prechronic, mechanistic, and toxicokinetic and mechanistic studies.” The NTP did prechronic tests before the long term studies.
>
> “Standard animal bioassays generally begin dosing after the animals are several weeks old, when many organ systems are mature. This could lead to an understatement of risk, because an accepted concept in the science of carcinogenesis is that young animals are usually more susceptible to the carcinogenic activity of a chemical than are mature animals (McConnell, 1992).”

FDA Misrepresentation #7: The FDA has evaluated the FCC's human exposure limits for RFR and come to a determination that the limits are protective based on its scientific review of the limits.

Fact: The FDA has never released any science based report that evaluates the FCC's human exposure limits for RFR and determined that FCC limits are protective. Instead, all the FDA has produced is its 2020 literature review *focused only on cancer and cell phones.* This literature review is not a systematic review, not a risk assessment, nor is it a review of FCC limits-whereby levels of exposure in studies would be compared to the FCC RFR limits.

- Examples of FDA's misrepresentations are that they have done a science based review of the FCC RFR human exposure limits to make a determination that FCC's limits are protective of public health.
- Evidence that FDA's representation that it evaluated the adequacy of FCC limits is erroneous.

Examples of FDA's misrepresentations that they have done a science based review of the FCC RFR limits to make a determination that FCC's limits are protective of public health.

September 9, 2019 FDA Letter to Merkley and Eshoo clearly states that the FDA reviewed the science and the RFR limits to determine if they were adequate.

> *"We appreciate the opportunity to provide an overview of the substantial body of evidence that has informed our determination that the current safety standard for RFR exposure remains appropriate."*
>
> *"FDA's conclusion that the current safety limits for cell phone RFR exposure remain acceptable for protecting the public health is supported by the considerable body of peer- reviewed scientific publications."*

The FDA's online webpage "Scientific Evidence for Cell Phone Safety[98]" states:

> *"The state of scientific knowledge continues to demonstrate that: The current limit on radio frequency (RF) energy set by the Federal Communications Commission remains*

[98] Health, Center for Devices and Radiological. "Scientific Evidence for Cell Phone Safety." *FDA*, FDA, Feb. 2020. *www.fda.gov*, https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety.

acceptable for protecting[99] *the public health. The FDA recently provided an updated assessment of the current limits based on the currently available scientific evidence (see Letter from the FDA to the FCC on Radiofrequency Exposure…"*[100]

The FDA's April 24, 2019[101] letter submitted to the FCC regarding RFR human exposure limits has only one paragraph on the issue, concluding:

> *"the available scientific evidence to date does not support adverse health effects in humans due to exposures at or under the current limits, and that the FDA is committed to protecting public health and continues its review of the many sources of scientific literature on this topic."*

The October 18, 2017 email from FDA's Kassiday to Scarato[102] states:

> *"The current safety limits established by the FCC are adequate to protect the public based on the peer reviewed literature."*
> *"Currently we believe that the safety limits are adequate to protect the public."*

The National Cancer Institute presented to the New Hampshire State Commission on 5G in a 7/16/2020 email that the FDA had done an assessment of US RFR limits.

> *"The FDA recently provided an updated assessment of the current limits of RF energy based on the currently available scientific evidence (see Letter from the FDA to the FCC on Radiofrequency Exposure)." (page 38 of New Hampshire Commission Report on 5G)*[103]

The FDA's 2020 letter to U.S. Senator Baldwin[104] states:

> *"Based on this extensive risk analysis, our determination remains consistent that there is no scientific evidence that warrants a change in cell phone safety limits, and that there is insufficient evidence to demonstrate a causal link between cell phones and cancer in the population. We believe that all of the questions contained in your constituent's letter are answered in the publicly available information, and I have included links below to the relevant information."*

The FDA's letter to Eshoo and Merkley creates the illusion that a risk assessment was done, stating:

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[99] "Radio Frequency Safety." *Federal Communications Commission*, 2 Mar. 2011, https://www.fcc.gov/general/radio-frequency-safety-0.
[100] "Letter from the FDA to the FCC on radiofrequency exposure." (April 14, 2019) https://www.fda.gov/media/135022/download.
[101] "FDA letter to Mr. Julius Knapp Chief Office of Engineering and Technology." U.S. Federal Communications Commission. (April 24, 2009). https://ecfsapi.fcc.gov/file/10815418118189/13-84.pdf.
[102] "Email from FDA's Kassiday to Scarato." (October 18, 2017) https://ehtrust.org/wp-content/uploads/FDA-communications-Scarato-PDF-2019.pdf
[103] "Page 38 of New Hampshire Commission Report on 5G." (November 1, 2020). http://www.gencourt.state.nh.us/statstudcomm/committees/1474/reports/5G%20final%20report.pdf.
[104] " FDA's Letter to US Senator Tammy Baldwin." (September 09, 2020) https://ehtrust.org/wp-content/uploads/FDA-9_10_-2020-Letter-Senator-Tammy-Baldwin-.pdf

"The gold standard for the assessment of risk to public health remains the data and information that is available from studying effects on humans. Animal and laboratory studies can provide useful scientific information, but data on human health is the most informative where it is available. In the case of cell phone handsets, there is abundant evidence to support FDA's conclusion from epidemiological studies, public health surveillance data and supportive laboratory studies. The information on which FDA has based its conclusion is summarized below, together with a description of the methods that the Agency uses for undertaking risk analysis and other relevant scientific information."

Evidence that FDA's representation that it evaluated FCC limits is erroneous.

The only FDA report on cell phone radiation the FDA has publicly presented is the 2020 literature review and it fails to meet even the minimum criteria for being a review of the FCC human exposure limits. First and foremost, the FDA's literature review is void of information on the actual FCC regulations for cell phone radiation. The FCC requires mobile phone manufacturers to demonstrate compliance with an SAR level of 1.6 watts per kilogram (averaged over one gram of tissue) but this is not mentioned anywhere.

There are no tables with the studies comparing the various exposure levels in research studies to the FCC limits. The FCC human exposure testing and rules on laptops, tablets, Wi-Fi routers, smart speakers and wireless printers are not even mentioned. (While the FDA does mention *whole body limits* in reference to the NTP study, these are not the same as the localized FCC limit used for premarket cell phone compliance tests.)

In addition, the FDA also does not mention any determination on the adequacy of cell phone testing protocols- a key part of FCC rules on human exposure.

In order to determine if FCC limits are adequate, the FDA should have followed a stated methodology for example, identified a list of risk assessment-quality studies and identified a no observed adverse effect level based on a weight-of-evidence evaluation on recent science. The FDA should have shared what the safety margin is and how it remains appropriate based on an up to date assessment of the totality of science. Yet no evidence of an evaluation of FCC limits exists.

As documented in detail earlier in our section "The 2020 Literature Review is not a risk assessment" the literature review does not even meet best practices for systematic review and human health assessments, much less basic requirements of a safety review of FCC limits.

In correspondence with Scarato (page 31)[105] about the FDA's refusal to act on this issue after being presented numerous research studies showing harm, FDA's Daniel Kassiday, Radiation Safety Engineer at U.S. Food and Drug Administration referenced an European SCENIHR Report. When Scarato asked, "Is the FDA's stance to consider the SCENIHR opinion as the FDA's opinion?" the FDA responded, "the FDA comes to its own conclusions."

In short, the FDA specifically states that the FDA itself makes its own determinations. Yet the FDA has not publicly shown any evidence of a science-based method to make a determination on RF limits.

In sharp contrast to the FDA's lack of action or methodology, a 2021 study[106] by the Environmental Working Group published in the journal Environmental Health used benchmark dose modeling as an approach to develop health-based exposure limits for RFR based on animal toxicology data from the NTP study. Their analysis suggests a limit of 0.2–0.4 mW/kg whole body SAR for young children, *far far lower than FCC whole body SAR limits.*

FDA Misrepresentation #8: The FDA states they "continually monitor the scientific studies" yet show no evidence of *regular* research monitoring nor regular scientific reviews.

Fact: The FDA shows no documented evidence of regular research reviews nor regular research monitoring. The FDA publicly states that the agency will act if credible science shows harm but has never defined what it deems as credible, nor the process by which they evaluate or monitor the RFR issue.

There are no monthly or yearly reports, no research updates and no publicly available notes or agendas from meetings on the issue of RFR. Emails and letters to and from the FDA *over the years* have not shown a transparent process where the FDA lists and evaluates research studies. For example, there was no public report on the website *until 2020* when the Literature Review was released. Nor have any emails or letters had any reference to an FDA report until 2020. Furthermore, the FDA website remained unchanged for years and was not updated until February 2020 despite numerous published studies showing adverse effects.

If the FDA is engaged in "continuous" monitoring of the science, the FDA's method and process have been kept a secret from the public.

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[105] "FDA Response to Scarato." (January 09, 2019) https://ehtrust.org/wp-content/uploads/FDA-communications-Scarato-PDF-2019.pdf

[106] Uche, U.I., Naidenko, O.V. "Development of health-based exposure limits for radiofrequency radiation from wireless devices using a benchmark dose approach." *Environ Health* 20, 84 (2021). https://doi.org/10.1186/s12940-021-00768-1

- Examples of the FDA's misrepresentation that they "continuously monitor" the science.
- Scientific research published after the FDA literature review time frame that the FDA has not shared with the public, nor reviewed in public documents.

Examples of the FDA's misrepresentation that they "continuously monitor" the science.

FDA's online webpage "Scientific Evidence for Cell Phone Safety" states:

> *"The FDA's doctors, scientists and engineers continually monitor the scientific studies and public health data for evidence that radio frequency energy from cell phones could cause adverse health effects. If a credible risk is detected, the FDA will work closely with other federal partners to mitigate the risk."*

In a July 15, 2020 letter to the New Hampshire Commission (found in the New Hampshire Commissions 5G Report page 41) the FDA stated:

> *"FDA's doctors, scientists and engineers continually monitor the scientific studies and public health data for evidence that radio frequency energy from cell phones could cause adverse health effects."*

In the September 9, 2019 FDA Letter to Representative Eshoo the FDA states, *"FDA will continue to monitor scientific information as it becomes available regarding the impacts of 5G."*

Scientific research has been published after the FDA literature review time frame. Yet the FDA has not shared these studies with the public, nor reviewed the research in public documents.

Numerous peer reviewed studies and systematic reviews have indicated adverse biological effects from wireless radiation. However the FDA has not shared these studies with the public nor released any report indicating the FDA has reviewed the publications.

The Environmental Working Group published a study in *Environmental Health* analyzing the findings of tumor and heart damage from the National Toxicology Program study and concluded that FCC limits should be strengthened by 200 to 400 times to protect children according to current risk assessment guidelines (Uche 2021).

European Parliament requested a research report "Health Impact of 5G" released in July 2021 concluding that commonly used RFR frequencies (450 to 6000 MHz) are probably carcinogenic for

humans *and* clearly affect male fertility with possible adverse effects on the development of embryos, fetuses and newborns.

A landmark three part **2021 research review** on effects to wildlife published in R*eviews on Environmental Health* by U.S experts including former U.S. Fish and Wildlife senior biologist Albert Manville states current science should trigger urgent regulatory action citing more than 1,200 scientific references which found adverse biological effects to wildlife from even very low intensities of non ionizing radiation with findings of impacts to orientation and migration, reproduction, mating, nest, den building and survivorship (Levitt et al., 2021a, Levitt et al., 2021b, Levitt et al., 2021c).

- **February 2020-** Scientists of the National Institute of Environmental Health Sciences National Toxicology Program published a study finding "significant increases in DNA damage" in groups of male mice, female mice and male rats after just 14 to 19 weeks of exposure to RFR (Smith-Roe et al., 2020).
- **March 2020**- Yale researchers published a study supported by the American Cancer Society linking thyroid cancer to cell phone use in people with a type of common genetic variation (Luo et al., 2020).
- **May 2020-** A meta analysis of 300 peer-reviewed scientific publications (1990-2015) describing 1127 experimental observations in cell-based in vitro models on RFR published in *Environmental Research* found less differentiated cells such as epithelium and spermatozoa are more sensitive to RF (Halgamuge et al., 2020).
- **May 2020**- A review on real world exposure to 5G published in *Toxicology Letters* found that 5 G will have systemic effects as well as adverse effects to the skin and eyes (Kostoff et al., 2020).
- **November 2020-** A systematic review and meta-analysis of case-control studies found evidence that linked cellular phone use to increased tumor risk (Choi et al., 2020).
- **February 2021**- A 4G study found kidney inflammation and damage to the testes in mice (Hasan et al., 2021).
- **March 2021**- The Switzerland Institute of the Environment expert published review found increased oxidative stress in the majority of animal studies and cell studies with exposures within regulatory limits (Schuermann et al., 2021).
- **July/August 2021**- Two systematic reviews find harm to sperm (Sungjoon et al, 2021, Yu et al., 2021).
- **August 2021**- A review on impacts to the thyroid found RFR might be associated alterations in thyroid hormone levels, with a possible disruption in the hypothalamic-pituitary-thyroid axis (Alkayyali et al., 2021)
- **August 2021-** 2400 MHz affects the structural integrity of the hippocampus in mice (Hasan et al., 2021).
- **August 2021-** A review summarizes the effects of EMR on the neurotransmitters in the brain (Hu et al., 2021).
- **September 2021**- A systematic review on the effects of RFR to male reproductive hormones found that wireless can decrease testosterone reduction (Maluin et al, 2021).
- **September 2021-** A review on the genetic effects of non-ionizing electromagnetic fields found DNA strand breaks, micronucleus formation, and chromosomal structural changes (Lai 2021).
- **September 2021**- A systematic review published in the Annals of the New York Academy of Sciences found that neuronal ion channels are particularly affected (Bertagna et al 2021).
- **October 2021**- A review in the International Journal of Oncology describes how EMFs lead to dysfunction of ion channels which lead to reactive oxygen species/free radical overproduction providing " a complete picture" of how exposure may indeed lead to DNA damage and related pathologies, including cancer," (Panagopoulos et al. 2021).

- **October 2021-** Scientific modeling study finds RF absorption of a mosquito is 16x higher at 60 GHz than at 6 GHz indicating 5G future technologies "can cause dielectric heating and have an impact on behaviour, development and possibly spread of the insect" substantiating calls to ensure pollinators are protected before 5G deployment.

FDA Misrepresentation #9: FDA inaccurately states there is "scientific consensus" that safety is assured.

Fact: The FDA repeatedly and inaccurately states there is "scientific consensus" that cell phones are safe despite the fact that the FDA is fully aware that hundreds of scientists and thousands of medical doctors are warning that the science indicates serious health effects and they recommend that the public *should* reduce exposure. The FDA also states that there is a scientific consensus that cell phones specifically do not cause cancer despite the fact that numerous authors in numerous published papers conclude RFR is a carcinogen.

As Dr. Ronald Melnick, now retired from 28 years as an NIH scientist, states in his letter to the FDA:

> "The statement on the FDA website (https://www.fda.gov/radiation-emitting-products/cell-phones/do-cell-phones-pose-health-hazard) that there is a "scientific consensus on cell phone safety" is totally wrong and should be removed since there is no scientific consensus supporting this claim. In contrast, numerous experts in the field have reported evidence that current levels of cell phone radiation can be harmful to human health."

- Examples of FDA's misrepresentation of "scientific consensus" for cell phone and RFR safety.
- Documentation that FDA's statement of consensus is unfactual because thousands of doctors and scientists are warning that RFR is not safe and recommending people reduce exposure.
- Industry connected scientists admit there is "no consensus."

Examples of FDA's misrepresentation of "scientific consensus"

FDA's website page "Do Cell Phones Pose a Health Hazard?"[107] has a section entitled:

> "*Scientific Consensus on Cell Phone Safety"*

[107] "Do cell phones pose a health hazard?" U.S. Food and Drug Administration. (2020) https://www.fda.gov/radiation-emitting-products/cell-phones/do-cell-phones-pose-health-hazard.

Another FDA website page "Radio Frequency Radiation and Cell Phones"[108] states:

> *"Scientific consensus shows that non-ionizing radiation is not a carcinogen and, at or below the radio frequency exposure limits set by the FCC, non-ionizing radiation has not been shown to cause any harm to people."*

Documentation that FDA's statement of "scientific consensus" is unfactual.

Many scientists state scientific evidence is now sufficient to trigger protective action by the FDA citing a mounting body of credible published research has linked RFR exposure to numerous effects including: genetic damage, oxidative stress, damaged sperm, brain cancer, thyroid cancer, altered brain development, memory damage, and impacts to the endocrine, and reproductive systems. Yet the FDA does not even cite or reference that such a body of evidence even exists and the FDA inaccurately states that there is a "scientific consensus" for safety. Thousands of doctors, scientists and medical organizations are calling for urgent action on RFR due to the body of scientific evidence showing harm.

Over 3,500 doctors and scientist have signed[109] onto the 2020 Consensus Statement of UK and International Medical and Scientific Experts[110] calling for an "immediate moratorium on 5G, wireless smart metering and any other new RF emissions" as well as the "establishment of public safety limits to be biologically protective against adverse health effects" because of the "exponential increase in ambient radiofrequency radiation." The consensus statement reads:

> *"In truth, we are now beyond the point of precaution and protection of vulnerable groups is an emergency. RF has been shown to cause widespread, multisystem health detriment and effects on the immune system have been demonstrated in some peer-reviewed published studies."*

There have been appeals and position statements for decades[111]. For example, the International EMF Scientist Appeal[112] by 255 scientists from 44 countries who have published specifically on bioelectromagnetics in the peer-reviewed literature have collectively petitioned the WHO and the UN for immediate measures to reduce public exposure and create protective safety limits.

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[108] "Radio Frequency Radiation and cell phones." U.S. Food and Drug Administration. (2020) https://www.fda.gov/radiation-emitting-products/cell-phones/radio-frequency-radiation-and-cell-phones.

[109] "Doctors & Scientists Appeals for Stronger Electromagnetic Radiation Regulations." (May 17, 2017)
[110] "2020 non-ionising radiation consensus." (October 11, 2020)
[111] "Doctors & Scientists Appeals for Stronger Electromagnetic Radiation Regulations." (May 17, 2017)
[112] Redazione, L. "International Appeal: Scientists Call for Protection from Non-Ionizing Electromagnetic Field Exposure". *European Journal of Oncology and Environmental Health*, vol. 20, no. 3/4, Dec. 2015, pp. 180-2, https://www.mattioli1885journals.com/index.php/EJOEH/article/view/4971.

In Europe, over 400 scientists and medical doctors signed onto the 5G Appeal[113] calling for a halt to 5G infrastructure because “RF-EMF has been proven to be harmful for humans and the environment.”

In April[114] and September of 2021 scientists sent letters to President Biden with 12 recommendations, accompanied by a scientific briefing on the health and environmental effects of 5G that has now been sent to policymakers worldwide. In 2019 US medical professionals sent a letter to President Trump[115] calling for urgent action on 5G and wireless networks.

Clearly there is not a scientific consensus that RFR is safe.

Even industry connected scientists admit there is no consensus.

According to Dr. Emilie van Deventer, Head of the World Health Organization’s EMF Project (a group[116] documented to have conflicts of interest), as quoted in The Daily Princetonian in 2015, “The data is gray. It’s not black and white...There is no consensus, it’s true. There’s a big group and a little group, but it’s still two groups. I can’t tell you that there’s one group that is completely correct.”

On May 19th 2016 at the Swedish Radiation Safety Authority's seminar in Stockholm, journalist Mona Nilsson asked Emilie van Deventer, “What is your reply to those 220 scientists? [referring to the International EMF Scientist Appeal] Why should the public trust you more than those 220 scientists?” Emilie van Deventer responded “It’s 220 versus uh, I don’t know.. what is your reference..” and did not discuss it further. Watch the interaction at the Seminar.

FDA Misrepresentation #10: FDA states that children and pregnant women are adequately protected by FCC limits despite no publicly available review on the unique vulnerability of children, pregnant women and the fetus.

Fact: The FDA repeatedly presents that there is no need for children or pregnant women to reduce exposure because the FDA has determined that FCC exposure limits are adequately protective. Yet the FDA has shown *no evaluation of the research on children's unique*

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[113] “EHT Open letter. An Overview of the Health and Environmental Effects of 5G, 4G and Wireless Radiofrequency Radiation.” (April 2021)
[114] “Letter to Biden on Infrastructure/FCC from Environmental HealthTrust.” (April 21, 2021)
[115] “Dozens of US Doctors and Healthcare Practitioners send letter to President Trump calling for a Moratorium on 5G Press Release.” (December 13, 2019)
[116] Hardell L. “World Health Organization, radiofrequency radiation and health - a hard nut to crack (Review).” Int J Oncology. 51:405-413. 2017. https://www.spandidos-publications.com/10.3892/ijo.2017.4046

vulnerability, nor any evaluation of effects during pregnancy nor any systematic evaluation of how FCC limits have ***incorporated recent research on*** *children.* FDA's 2020 issued Literature Review did not focus on children's vulnerability. In fact, only three studies in the entire Review were noted in the FDA report as involving children.

- Published research finds children are more vulnerable because their developing brain is more sensitive.
- Examples of the FDA stating that they reviewed the research on children, pregnant women and the fetus.
- FDA states the federal office that performs state of the art scientific evaluations to reach conclusions about potential human health hazards does not need to do an evaluation because the FDA can do it "if necessary"- regarding the impact to children and pregnancy:

Published research finds children are more vulnerable because their developing brain is more sensitive.

The American Academy of Pediatrics recommends reduced cell phone exposure for children. Published research that the FDA *has not shown it has reviewed* indicates children are more vulnerable for numerous reasons. They absorb proportionately more RFR[117] into their brains and bodies because they have thinner, softer skulls, smaller bodies and shorter distances to critical brain regions as well as more electrically conductive tissue compared to adults. Furthermore, even if exposures were the same, children and the fetus are more vulnerable because their brains and bodies are rapidly developing, and even small exposures can have heightened effects, some of which will not be noticed in the population until years later.

Then Executive Director of EHT, Theodora Scarato sent and shared several studies on children to the FDA, showing higher exposures. For example, on November 8, 2017, Scarato sent the FDA staff a published 2017 paper that found in certain positions the maximum 700 MHz and 2600 MHz RFR exposure levels in brain tissues of young children models can be up to 61% and 78% higher than in adults.

Examples of the FDA representing that they reviewed the research on children, pregnant women and the fetus.

FDA's website page "Children and Teens and Cell Phones" states:

> *"Current scientific evidence does not show a danger to any users of cell phones from radio frequency (RF) energy, including children and teenagers. There are also simple*

[117] Fernández, C., de Salles, A., Sears, M., Morris, R., & Davis, D. (2018). "Absorption of wireless radiation in the child versus adult brain and eye from cell phone conversation or virtual reality." Environmental Research, 167, 694-699. https://doi.org/10.1016/j.envres.2018.05.013

steps that anyone, including children and teenagers, can take if they would like to reduce RF exposure."

The FDA then provides four short tips and references to an European epidemiological study (the MOBI-KIDS study) that has yet to be published, stating, "*As with all other information, the FDA will continue to monitor scientific information and assess the results of this study as it becomes available."*

FDA's Kassiday repeatedly stated in an email exchange (page 50 of 66) to Scarato that:

"*Our conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women.*"

In the email communication (page 17 of 66) the FDA responded to questions related to pregnancy by providing two references and concluding, "*These studies suggest that the current safety limits are adequate to protect pregnant mothers and offspring."* However these two references were not FDA's safety limit evaluations nor a risk assessment. Equally important they did not show safety but instead the need for more research in several areas.

When Scarato queried (page 40- of 667) that *"Children absorb the radiation deeper into their brain and body. Please explain why the FDA states "The scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers."* to this the FDA responded with the same answer it had for the question on pregnancy and added, "*Our current conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women."*

When Scarato queried (page 61 of 66), "*What proof of safety is there that pregnant women are protected when it comes to this radiation. They are placing laptops on their bellies. Has the FDA looked at research on impacts on pregnancy? If so, please share what studies have been reviewed*" the FDA responded:

"The FDA has been reviewing RF published reports since the early 1990's. FDA has meetings with interested organizations and working with the National Academy of Sciences, and conducted PubMed literature searches over this time period." and referenced the WHO (which, notably, has not done any review on RFR since 1993), ICNIRP (a 13-member group with no oversight) and a 2015 European Report. Kassiday stated, "*For the most up to date review of this specific topic a PubMed search will provide an excellent background."* Yet the FDA did not share its scientific references or any report involving pregnant women.

FDA states the federal office that performs state of the art scientific evaluations to reach conclusions about potential human health hazards does not need to do an evaluation because the FDA can do it “if necessary” regarding children and pregnancy:

In the email correspondence with FDA’s Kassiday (page 39 of 66) Scarato detailed science showing harm to children and examples of children using wireless devices close to their bodies. She asked the FDA why it would not ask the NTP Office of Health Assessment and Translation (OHAT) to do a literature-based scientific evaluation to reach conclusions about potential human health hazards, stating, “*I would think a systematic review is in order considering the exposure to babies and children for a lifetime.*”

To this FDA’s Kassiday responded:

> *“There is no need for NTP to do this work for the FDA. This can be done by the FDA if necessary. Also, there are already many systematic reviews available.”* However, because the FDA did not reference any systematic reviews to substantiate this statement, Scarato then asked, *“Please list those you are referring to. As far as I know, there are no systematic reviews that have been done and the US has not looked at this for over 20 years.”* And in response the FDA referenced the industry-affiliated IEEE International Committee on Electromagnetic Safety.

Citizens Petition of Frederick S. Mayer

In 2017, the FDA denied the Citizens Petition of Frederick S. Mayer. (See FDA Denial of Petition Docket FDA 2013-P-1374 to Frederick S. Mayer, July 17, 2017). In their denial they state they have addressed his issues but in reality they have not as the FDA never addressed research on non cancer issues and children's development and pregnancy. In addition, the FDA asserts research showing decreases in cancer as proof of cell phone safety despite the CDC and Annual reports to the Nation that specifically show increases in children's cancers including brain cancers.

Mayer had specifically raised the issue of “*adverse health and neurological impacts of EMF/RFR. Children are more vulnerable than adults, and children with chronic illnesses and/or neurodevelopmental disabilities are even more vulnerable.”* Mayer raised non cancer issues such as *“sperm collapse, fetal damage, ADHD, infertility…”* Yet in response to his request for the FDA to address potential health risks to children they said his request was “*moot as the following independent actions relevant to these requests have already been undertaken, or are currently being undertaken, by the FDA.”* Specifically the FDA stated that it had listed on its website studies being undertaken in regards to children referring to this 2017 FDA webpage (https://web.archive.org/web/20190404045156/https://www.fda.gov/Radiation-EmittingProducts/

RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/CellPhones/ucm116335.htm).

However in the February 10, 2020 website update, this FDA page was changed to Scientific Evidence of Cell Phone Safety with no information on non cancer research on as it relates to children and numerous misrepresentations regarding the NTP study. See details in Misrepresentation #6: The FDA misrepresents the significance of its own sponsored $30 million U.S. National Toxicology Program (NTP) animal study findings and presents inaccurate facts regarding the study and Misrepresentation #10: The FDA misrepresents that children and pregnant women are adequately protected by FCC limits despite no publicly available review on the risks posed by the unique vulnerability of children, pregnant women and the fetus).

Notable on their webpage Scientific Evidence of Cell Phone Safety the FDA asserts that cancer rates are decreasing as proof of cell phone safety referencing the Surveillance, Epidemiology, and End Results (SEER) database maintained by the National Cancer Institute (NCI) at the National Institutes for Health (NIH) which they says shows "that brain cancer rates are not increasing in the United States despite the significant increase in the number of cell phone users."

However cancers are increasing in children and young adults.

- 2021: The Annual Report to the Nation on the Status of Cancer jointly issued by the American Cancer Society, the Centers for Disease Control and Prevention, the North American Association of Central Cancer Registries, and the National Cancer Institute found **overall cancer incidence rates continue to increase among females, children, and adolescents and young adults.**[118]
- 2018 CDC: The US CDC presented new findings in 2018 of increasing brain, renal, hepatic, and thyroid cancers among individuals under 20 years old in the USA after analyzing 2001–2014 data from 48 states covering 98% of the US population. Siegel 2018
- A study published in the Journal of the National Cancer Institute examined AYA cancer incidence trends in 41 countries over a 15-year period found "striking trends" for increases in thyroid and testicular cancer, with statistically significantly increasing rates observed in 33 and 22 countries[119].

The way people are using devices has dramatically changed in the last two decades. At first people used cell phones to their head - which would result in high RFR levels into a part of the brain- but now people use phones in front of their body to text or exchange videos and photos - creating more dispersed RFR exposures to the front of the body- and people carry phones in front and back pockets- creating intense exposure into the lower torso. Further the way phones are designed have changed. Handsets used to have antennas off the top of the phone but now have antennas at various points around the edges of the phone which again changes the

[118] Islami, Farhad, et al. "Annual Report to the Nation on the Status of Cancer, Part 1: National Cancer Statistics." *JNCI: Journal of the National Cancer Institute*, vol. 113, no. 12, Dec. 2021, pp. 1648–69. *Silverchair*, https://doi.org/10.1093/jnci/djab131.
[119] Gupta, Sumit, et al. "International Trends in the Incidence of Cancer Among Adolescents and Young Adults." *JNCI: Journal of the National Cancer Institute*, vol. 112, no. 11, Nov. 2020, pp. 1105–17. *Silverchair*, https://doi.org/10.1093/jnci/djaa007.

exposures into the body depending on its position. For example a newer model phone held at ear will have higher RFR into the thyroid than early phones that had the pull out antennas at top of the phone. These changes in exposure can impact which tissues receive the most intense exposures. Recent publications have noted the increases in thyroid and colon cancer and hypothesized that it could be due to these changes in wireless phone design and use patterns (Davis et al. 2020, Carlberg et al. 2020)[120]. Research is needed to address these questions and yet the US is not actively pursing such studies as far as we know.

FDA Misrepresentation #11: The FDA presents that cell phones are safe in body contact positions, *even if the radiation levels exceed U.S. FCC regulatory limits.*

Fact: The FDA knowingly allows the American public to be exposed to RFR levels in excess of the regulatory limit yet the FDA's website pages have images of smiling people with cell phones against their heads—communicating the message that phones are safe near the body. The FDA website does not have any warnings to the public explaining that all cell phone manufacturers have special instructions—fine print warnings—buried deep in the cell phone manuals that say to keep the phone at specified distance away from the body: from 5 to 25 millimeters[121].

In summary, as the evidence we share below shows, the FDA is aware that FCC limits are exceeded when phones are tested in body contact position and well aware that the public has no idea of the excessive RFR levels. The FDA says there is "a large safety margin" that is protective yet cannot answer how large the safety margin is nor at what RFR level past the FCC regulatory limit the FDA would act. The FDA shows no review of recent research to even determine at what level above the FCC limits the FDA would act.

Further, the FDA misrepresents that a 50 times safety factor exists for the FCC's RFR limits for cell phone radiation. The result of the FDA misrepresentation is that the media, the public, government agencies and even the companies themselves think that there is a 50-times safety factor in regards to local cell phone limits. The FDA does not explain that there is no 50 fold safety factor for local tissue SAR. Even when the FCC and Apple put forward this misrepresentation in legal filings and testimony, the FDA did not clarify it.

- FDA misrepresents that there is a "50- fold" safety margin in the regulatory limits.
- The FDA is fully aware of manufacturer safety instructions that state the phone should not be in body contact and instead kept at a specified distance.

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[120] Carlberg M, Koppel T, Hedendahl LK, Hardell L. Is the Increasing Incidence of Thyroid Cancer in the Nordic Countries Caused by Use of Mobile Phones? Int J Environ Res Public Health. 2020 Dec 7;17(23):9129. And Devra L Davis , Aaron M. Pilarcik and Anthony B. Miller, Increased Generational Risk of Colon and Rectal Cancer in Recent Birth Cohorts under Age 40 – the Hypothetical Role of Radiofrequency Radiation from Cell Phones, Annals of Gastroenterology and Digestive Disorders, 2020,

[121] Fine Print Warnings EHT website https://ehtrust.org/fine-print-manufacturer-radio-frequency-radiation-warnings/

- The FDA was sent research confirming cell phones in body contact positions violate RF limits.
- The FDA defends its lack of action on FCC RFR limit violations by stating there is a "large safety factor" yet cannot define what the "large safety factor" actually is.
- The FDA defends the yet unknown "large safety factor" as "adequately protective."
- The FDA admits the public is unaware of these fine print warnings because the information is not easily accessible and most consumers do not read their manuals.
- Wireless companies have long promoted the inaccurate illusion that the safety factor for phones against the body is 50 using the same tactics as the FDA.
- The Media repeats the FDA's Misrepresentation about the 50-times Safety Factor

The FDA is fully aware of manufacturer safety instructions that state the phone should not be in body contact and instead kept at a specified distance.

The FDA knows that before cell phones come on the market, manufacturers test cell phones for radiation in standardized test positions—positions set decades ago when phones were carried in holsters. All of these standard use positions allow *a space between the phone and the body.* The U.S. FCC regulations do not ensure cell phones are radiation tested in "real world use" positions where the phone is in body contact with the body. Examples of real world use positions that manufacturers' instructions would caution are not the "as tested" positions include: a cell phone in a tight pants pocket or tucked in spandex pants; a cell phone in the bra; a cell phone resting against the abdomen; a cell phone pressed against the neck so that the edge is touching the neck and thyroid area; a cell phone angled so an edge is against the skull (not ear which is allowed to absorb more RFR than the body). The fine print warning instructions in cell phones state that the phone should be at a specified distance from the body in order to maintain FCC compliance.

Similarly, many laptop models are *not* tested in body contact positions such as resting on the lap, snug up to the abdomen. Further, wireless devices such as Wi-Fi routers, Wi-Fi printers, wireless thermostats/cameras and smart speakers are also not tested in body contact positions and, in fact, have fine print warnings stating they should be held at 20 cm (about 8 inches) from the human body.

The FDA was sent research confirming cell phones in body contact positions violate RF limits.

Importantly, numerous investigations and published studies have shown that when cell phones are tested in body contact positions, the radiation exposure levels will significantly exceed the U.S. FCC limits[122]. Gandhi 2019 examined data from 450 cell phone models from the French

[122] Gandhi, O.P. (2019). Microwave Emissions From Cell Phones Exceed Safety Limits in Europe and the US When Touching the Body; 2017 investigation by the Canadian Broadcasting Corporation "The secret inside your cell phone"; Kang, Gang, and Om P. Gandhi. "SARs for pocket-mounted mobile telephones at 835 and 1900 MHz." *Physics in Medicine and Biology* 47.23 (2002): 4301.

government agency ANFR—the national radiation assessment bureau—indicating that phones can emit 11 times over the U.S. FCC limit and 3 times over French limits in 9 out of 10 phones tested. In parallel, when laptops, computers or other wireless devices with regulatory separation are radiation tested in body contact positions, the RFR levels could violate FCC limits[123].

When EHT's Dr. Devra Davis and Theodora Scarato met with FDA staff at the FDA headquarters in 2014, this issue was extensively discussed. Shared information included recently published case reports of young women developing unusual breast cancers in locations underneath the antennas of the phone they had carried in their bra for years[124]. Scararto and Davis discussed how the American public was unaware that phones were not supposed to be in these close body positions—positions which allow consumers to be exposed to RFR levels that exceed the FCC's human exposure limits. We asked the FDA to inform the public and consumers about the fact that ***phones should be held at a distance from the body in order to be compliant with U.S. government regulations***. The FDA acknowledged that phones could exceed regulatory limits on several occasions in our communications with the FDA but did not take action.

Here are just a few examples of the research Theodora Scarato has sent to FDA staff regarding cell phone radiation exposure violations. Communications went to Daniel Kassiday, William Jung, Robert Och, CDRH Ombudsman, Jeff Shuren, Mary Pastel, Robert Ochs, Michael O. Hara, Brian Beard and Bakul Patel:

- On June 13, 2017 Scarato shared the latest research from the government of France that found hundreds of phones exceeded radiation regulatory limits when they were tested in body contact positions (starting at page 6 Scarato/FDA emails) and asked why the FDA had not taken action to inform the public.
- Scarato sent the FDA the March 12, 2019 IEEE published article (Gandhi 2019) that found if the French government measurements were done with U.S. FCC protocols, some cellphone radiation emissions would violate FCC limits up to 11 times.
- Scarato also sent the August 21, 2019 Chicago Tribune cell phone testing data showing phones violated FCC limits at body contact[125].

FCCs Lack of Response to EHT/Phonegate Association Letter: December 17, 2019: EHT and Phonegate Association write members of Congress with a letter and Background and Facts document on the urgent need for a hearing regarding cell phone radiation test procedures, due to the excessive radiation the phone can expose the user to in body contact positions.

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[123] Siervo, Beatrice, et al. "Numerical Evaluation of Human Exposure to WiMax Patch Antenna in Tablet or Laptop." *Bioelectromagnetics*, vol. 39, no. 5, John Wiley & Sons, Ltd, July 2018, pp. 414–22, https://doi.org/10.1002/bem.22128.

[124] West, John G., et al. "Multifocal Breast Cancer in Young Women with Prolonged Contact between Their Breasts and Their Cellular Phones." *Case Reports in Medicine*, vol. 2013, 2013, p. 354682. *PubMed*, https://doi.org/10.1155/2013/354682.

[125] *We Tested Popular Cellphones for Radiofrequency Radiation. Now the FCC Is Investigating.* - *Chicago Tribune*. Accessed 13 Dec. 2021.

Letters were also previously sent to the FCC on March 20, 2018. I surmise a key reason the FCC took no action after these letters was that on February 2, 2018 FDA's Shuren issued a statement that downplayed the NTP study cancer findings and took the position that cell phone radiation was safe even when exposures exceed limits due to the large safety margin.

The FDA defends its lack of action on FCC RFR limit violations by stating there is a "large safety factor" yet cannot define what the "large safety factor" actually is.

As an email chain between Scarato and the FDA dated May 31, 2017 details, Scarato asked, *"If the FDA is supposed to protect the public then they need to inform the public of the fine print instructions in the manual related to RF. Why is the FDA not acting on this and informing people of the fine print instructions on RF on cell phones and wireless devices? Children are carrying phones on their bodies, tucked in spandex pants and in bras and jeans in school classrooms. Can you please explain why the FDA is not ensuring the public is aware of the fine print warnings?"* FDA's Kassiday responded, *"There is a large safety factor included in the public exposure limit (see IEEE Std. C95.1-2005 Annex C, Rationale, for more information regarding this safety factor)."*

In response to the hundreds of tests finding RFR levels exceeded in France, on October 18, 2017 (FDA Scarato emails page 15) FDA's Kassiday wrote, *"We have asked the French Agency for a discussion of their studies and findings and conclusions. However, they have not responded as of the writing of this response."*

When Scarato asked, *"I am writing to ask if I understand correctly that the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor?"* FDA's Kassiday responded, *"FDA is not saying that it is OK to exceed a regulatory limit. We stated that there is a large safety factor built into these regulatory limits."*

On November 19, 2017 Scarato asked what exactly the FDA's "large safety margin" was (what numerical level) in an email, *"What does the FDA think the safety factor is for SAR exposure limits. Please state it.*" The FDA did not respond with an actual level.

The FDA defends the yet unknown "large safety factor" as "adequately protective."

In the May 31, 2017 email exchange Scarato asked the FDA why it was not informing the public about situations where cell phones will go to peak power, such as in a car. The FDA again stated, *"The safety factors set in place for RF exposure adequately protect the general public."*

On March 19, 2019 Scarato again also asked the FDA at what level the FDA would take action, asking, *"The FDA seems to be stating in prior email exchanges that even if FCC limits are violated, they do not need to do anything...Thus, is seems there is a SAR number at which the FDA believes is safe and one that is not safe... What is the cell phone SAR measurement that the FDA has identified that would trigger the FDA to act?"* Again the FDA did not respond with an actual level.

Scarato repeatedly asked the FDA to share the RFR threshold level that would trigger the FDA to act on February 3, 2018, April 5, 2018, June 2, 2018, June 11, 2018, November 6, 2018, March 2019 and several other dates but has never received a response that included the actual level that would trigger FDA action.

The FDA's only response to the question of the safety margin was talking about the 50-fold safety limit whole-body FCC limits. However this is not the regulatory limit for cell phone compliance and thus the FDA did not answer the question in regards to local tissue cell phone RFR exposure limits.

The FDA knowingly allows the American public to be exposed to RFR levels in excess of the regulatory limit. Scarato stated to the FDA (Page 35 FDA Scarato Emails), "Everyone I have spoken to is 100% unaware of this information buried in manuals. Please explain how the FDA has decided it is not their responsibility to inform the public on this."

The FDA's Kassiday responded:

> "*As any web search for "usability of user manuals" will reveal, there is a lot of concern and research on why most consumers ignore manuals and instructions. So it is not surprising that consumers are unaware of one particular fact in a manual when most consumers don't read anything in user manuals. The FDA has not done a survey and we are not aware if the FCC has."*

As shown in the preceding evidence, the FDA is aware that FCC limits are exceeded and defends its lack of action because of a "large safety margin" yet cannot answer how large the safety margin is nor at what RFR level past the U.S. regulatory limit the FDA would act. The FDA is aware that the public does not read their manuals and was provided evidence that people put phones in body contact positions. The FDA also misrepresents that it knows that the "large safety factor" itself (in addition to the FCC limits) protects the general public but shows no review of recent research on RFR safety factors to determine this level.

FDA Misrepresentation #12: The FDA misrepresents the existence of a 50 times safety margin in relation to cellphone radiation exposure limits.

The FDA is misrepresenting that a 50 times safety factor exists for the FCC's RFR limits for cell phone radiation.

Background on RFR limits and the 50-fold safety factor

There are two types of regulatory limits- set by the FCC in 1996- that address cell phone radiation emission exposure limits:

1. A peak spatial-average SAR limit, *also known as* a local SAR. This limit is for the tissues in close proximity to the transmitting phone (like your ear and brain and body). **This Local SAR does NOT have a 50-fold safety factor for brain or head tissue**

2. Whole body averaged SAR RFR limits- this averaged out over the whole body. For this limit, it is stated there is a 50-times safety factor for heating effects. (Note: EHT and many other scientists dispute that such a safety factor exists *even for the whole body limits. N*evertheless the issue of the 50-times safety factor is only relevant to whole body exposures and the FDA is well aware of this fact.)

Note: These local limits are further broken down into different limits for the head, body and extremities (hand, wrist, feet, ankles and the ear). There are different limits for the public and for occupational workers. In addition, there are a set of different limits for cell tower emissions.

When cell phones are brought to market the manufacturer must show cell phones meet the **local SAR exposure limit,** never the whole body SAR exposure limit. When one is addressing cell phone handsets, the relevant limit is the Local RFR limits.

FCC SAR LIMITS Specific Absorption Rate (SAR): a measure of the rate of energy absorption into a defined amount of tissue	**Whole-Body Average SAR W/kg W/kg= watts per kilogram**	**Local SAR Head and Trunk W/kg**	***Extremity SAR Hand, Wrist, Feet, Ankles and the Ear W/kg***
Occupational Exposure	0.4	8	20
Public Exposure	0.08	1.6	4

Averaging volume	Averaged over the whole body	Averaged over 1 gram of tissue.	Averaged over 10 grams of tissue.

Most of the public, elected officials and scientists (who are not bioelectromagnetic experts) do not understand the complexity of these limits, nor that there are two types of RF SAR limits. *(Additionally there are Maximum Permissible limits for cell tower emissions not addressed in this section.)*

However, the FDA is fully aware of the difference between the local and whole body limits but presents the issue in a way that omits that there are two types of limits, creating the false impression that there is a 50-fold safety factor for head/brain tissue in the regulatory limit.

The reality that there is no 50 times safety factor for the Local SAR Limit is a fact, even among scientists who do not believe that there are health effects from RFR at non heating levels. For example, the FCC states the threshold level at which harmful biological effects may occur is a Specific Absorption Rate (SAR) value for the whole body of 4 W/kg[126]. 4 W/kg is clearly not 50 times 1.6 W/kg (Local SAR) which is the regulatory limit for cell phones.

The self appointed small invite only group that calls itself the International Commission on NonIonizing Radiation Protection (ICNIRP) states in their latest 2020 guidelines that for Type 2 tissues **such as the head** the local adverse health effect threshold is a SAR of 20 W/kg averaged over 10 g. Therefore, the reduction factors in the 2020 ICNIRP guidelines are 2 for the occupational local exposures and 10 for the general public local exposures- ***not 50***. The ICNIRP 1998 guidelines also state that the SAR of 20 W kg is the local exposure level corresponding to the operational adverse health effect threshold for the Head and Torso- again putting forward a 10 fold reduction, not 50**. For the FCC local head/body limit of 1.6 w/kg, consider this- 20 divided by 1.6 is 12.5, not 50.**

Importantly, ICNIRP thresholds are based on heat only, not non thermal effects, yet *even if heat were the only harm,* the safety factor per ICNIRP for the head and torso local exposure limit is mathematically simply not 50.

FDA misrepresents that there is a “50-fold” safety margin in the regulatory limits.

Here are some examples where the FDA misrepresents that there is a “50- fold” safety margin in the regulatory limits.

FDA Shuren’s February 2, 2018 statement states:

[126] “RF Safety FAQ.” *Federal Communications Commission*, 25 Nov. 2015, https://www.fcc.gov/engineering-technology/electromagnetic-compatibility-division/radio-frequency-safety/faq/rf-safety.

> *"the [NTP}study was designed to test levels of radiofrequency energy exposures considerably above the current safety limits for cell phones to help contribute to what we already understand about the effects of radiofrequency energy on animal tissue. In fact, the current safety limits are set to include a 50-fold safety margin from observed effects of radiofrequency energy exposure."*

Most readers will think that the cell phone regulatory limit has a 50 fold safety factor.

The FDA never clarifies in any public communique that there are two types of limits and that the 50-fold statement only refers to whole body limits.

For example, in FDA's November 1, 2018 statement the word "whole body" is used but most people will have no idea that this means anything other than the safety limit. They will be unaware that there is a difference between the whole body and local limits.

> *"In fact, we only begin to observe effects to animal tissue at exposures that are 50 times higher than the current whole body safety limits set by the FCC for radiofrequency energy exposure."*

Wireless companies repeat the FDA's misrepresentation of the 50 times safety factor unaware it is non existent.

The result of the FDA misrepresentation is that the media, the public, government agencies and ***even the wireless companies themselves*** think that there is a 50-times safety factor for brain/head tissue in regards to local cell phone limits. Even when the FCC and Apple put forward this misrepresentation in legal filings and testimony, the FDA did not clarify it.

APPLE repeats the FDA's misrepresentation
Apple's legal briefs in the case Cohen v, Apple repeat the FDA's misrepresentation of a 50-fold safety factor in regards to cell phone's local limits. Importantly, this case centers around the fact that the iPhones were found to exceed the FCC regulatory limit of 1.6w/kg—the local, not whole body limit.

Apple's Jan 2, 2020 filing[127] directly references the FDA as the source of their information stating"

> *"The FCC has long recognized that a value 50 times greater than SAR 1.6 W/kg is the lowest level that could even potentially heat human tissue to a level that could cause adverse health effects."* ***Footnote 12 referring to*** *FDA, News Release, Statement from Jeffrey Shuren, M.D., J.D., Director of the FDA's Center for Devices and Radiological*

[127] https://storage.courtlistener.com/recap/gov.uscourts.cand.347222/gov.uscourts.cand.347222.62.0.pdf

Health on the Recent National Toxicology Program Draft Report on Radiofrequency Energy Exposure (Feb. 2, 2018) (RJN Ex. 4)

Apple's 5/01/2020 motion[128] also cites the FDA stating:

> Footnote 31 of the motion states, *"The FCC's limit on RF emissions has a fifty-fold safety factor built into it, as 1.6 W/kg is "one-fiftieth of the point at which RF energy begins to cause any unhealthful thermal effect."*
>
> *"...The FCC exposure limit for the general public is one-fiftieth of the point at which RF energy begins to cause any unhealthful thermal effect."); FDA, Press Release, Statement from Jeffrey Shuren, M.D., J.D., Director of the FDA's Center for Devices and Radiological Health*

Wireless companies have long promoted the inaccurate illusion that the safety factor for phones against the body is 50 using the same tactics as the FDA.

In March 31, 2015 testimony to the Maine Legislature about a wireless right to know law the Wireless Industry presented an argument about a phone to the head then immediately followed with a statement about the 50 fold safety factor. This likely will result in a reader thinking there is a fifty fold safety factor in regards to cell phones.

> *"Moreover, the FCC notes that **using a device against the body without a spacer will generally result in actual SAR below the maximum SAR tested;** moreover, a use that possibly results in noncompliance with the SAR limit should not be viewed with significantly greater concern than compliant use. The Commission also confirms in the NOI that its **RF exposure guidelines include a 50 fold safety factor** and this safety factor can well accommodate a variety of variables such as different physical characteristics and individual sensitivities - and even the potential for exposures to occur in excess of our limits without posing a health hazard to humans."*

The Media repeats the FDA's Misrepresentation about the 50-times Safety Factor

[128] https://storage.courtlistener.com/recap/gov.uscourts.cand.347222/gov.uscourts.cand.347222.104.0.pdf

Wikipedia's "Wireless device radiation and health" references the FDA's statements: despite the fact that the 50-fold safety margin is irrelevant to device safety limits.

> *"In a 2018 statement, the FDA said that "the current safety limits are set to include a 50-fold safety margin from observed effects of Radio-frequency energy exposure".*

The Chicago Tribune referenced the safety margin in its 8/21/2019 expose on how cell phones exceeded regulatory limits.

> *"The U.S. Food and Drug Administration, which shares regulatory responsibilities for cellphones with the FCC, responded to the study by assuring the public there was no danger to humans at "exposures at or under" safety limits. But the Tribune's testing, disputed by manufacturers, found results from some cellphones over the exposure standard, particularly when tested close to the body.*
> *Despite the changing ways people use phones, both the FCC and FDA said the current exposure limit protects the public. The agencies cite the 50-fold safety margin incorporated into the standard, as does CTIA, the industry association."*

FDA Misrepresentation #13: The FDA presents that the 5G network is safe despite not systematically reviewing the research on 5G's unique modulations and 5G's higher frequencies and despite the fact that the FDA has no authority in regards to cell towers or small cell tower installations.

- Statements by the FDA regarding 5G which create the illusion that the FDA is evaluating 5G networks and ensuring safety
- The FCC repeats the FDA's misrepresentation that it reviewed 5G and specifically 5G small cell infrastructure- despite the fact that the FDA has no authority in regards to wireless cell towers or infrastructure such as small cells.
- Documentation that the FDA is misrepresenting that they are reviewing the health effects of 5G.
- The FDA omits that it has no authority in regards to cell towers and 5G small cells and the FDA omits that it has never released any scientific review in regards to cell tower radiation exposure.

Statements by the FDA regarding 5G which create the illusion that the FDA is evaluating 5G networks and ensuring safety:

The FDA's webpage Scientific Evidence for Cell Phone Safety" has a section about 5G entitled "No New Implications for 5G" which starts out stating the FDA is "responsible" and then concludes by asserting that the FDA is "monitor[ing] the science":

> "*The FDA is responsible for, among other things, ensuring cell phones – and any radiation-emitting electronic product – are safe for the public to use. This includes understanding the health risks (if any) of new electronic products that emit radiation as they become widely available to the U.S. public, such as 5G cell phones. While many of the specifics of 5G remain ill-defined, it is known that 5G cell phones will use frequencies covered by the current FCC exposure guidelines (300 kHz-100 GHz), and the conclusions reached based on the current body of scientific evidence covers these frequencies. The FDA will continue to monitor scientific information as it becomes available regarding the potential impacts of 5G."*

The 2019 Letter by Representative Anna Eshoo and Senator Jeff Merkley to the FDA was specifically their request for FDA's research review on the health effects of 5G. Their letter stated:

> *"Hundreds of constituents have contacted our offices and those of our colleagues to raise concerns about the impact of cell phone RF emissions on human health especially as upcountry transitions to 5G."*
>
> *"Given that 95% of Americans own a cell phone having a better understanding of FDA analysis on this issue and how the agency reached the conclusion that current safety limits for cell phone RF energy exposure protect public health is critical. To that, we ask the FDA to share a summary of the research that the FDA has reviewed related to RF exposure in cell phones, including whether such research covers the RF ranges that may be used in the 5G and the criteria used to include or exclude studies in the FDA's review of research."*

In response, the FDA sent a Sept 9, 2019 letter to Representative Anna Eshoo and Senator Jeff Merkley purporting that FDA has reviewed the research and determined safety, even for 5G. The FDA's statements will all result in the reader being satisfied that the FDA has reviewed and is continuing to monitor the research on 5G and has determined it is safe. The FDA letter states:

> *"The agency has taken a comprehensive approach to evaluating scientific evidence regarding the impact of RFR exposure on human health."*
> *"We appreciate the opportunity to provide an overview of the substantial body of evidence that has informed our determination that the current safety standard for RFr exposure remains appropriate."*
> *"The Agency's ongoing evaluations include but are not limited to those frequencies currently being used by cell phones as well as those being considered for future uses (e.g., 5G)."*

In the letter under the section "FDA's findings" the FDA states:

> "the Agency has not seen credible evidence that the roll out of 5G handsets will lead to additional risk for the population."

In the letter there also is a one-paragraph section entitled, “No New implications for 5G” that details how 5G frequencies are non-ionizing with a “current body of scientific evidence” that has been well understood for many years” and concludes:

> *“Based on this information, the new 5G technologies are unlikely to pose additional risks to health for individuals. FDA will continue to monitor scientific information as it becomes available regarding the impacts of 5G.”*

The FCC repeats the FDA's misrepresentation that it reviewed 5G and specifically 5G small cell infrastructure- despite the fact that the FDA has no authority in regards to wireless cell towers or infrastructure such as small cells.

In a May 17, 2018 Congressional Hearing on FCC and FTC 2019 Budget Senator James Lankford asked the FCC Chairperson Ajit Pai about health issues because “there are some people who have raised health issues on 5G radiation.” FCC’s Pai, responded that, "we have consulted with the FDA and others for determining what those limits should be and we are confident that our standards are ones that are healthy for consumers"[129].

In 2018, after the FCC passed regulations fast tracking the deployment of small cell infrastructure nationwide, several federal and state elected officials wrote the FCC requesting information on the health effects of the infrastructure. In response, the FCC also sent letters.

On December 3 2018, Senator Richard Blumenthal (Connecticut) and Rep Anna G. Eshoo (California) sent a letter to the FCC requesting “the 5G safety determination from FCC and relevant health agencies” specifically in regards to small cell tower infrastructure close to libraries, schools and homes. The letter also asks for the” latest studies evaluating the health effects of high-band frequencies and 5G modulations. In response, FCC Commissioner Carr sent a December 17, 2018 letter to the officials referencing the FDA numerous times as providing continuing review of all the research on 5G as well as a determination that FCC limits are protective. Carr's letter asserts the FDA as the agency providing safety determinations, and a science review. Further the FCC’s letter omits the fact that the FDA has no authority in regards to wireless infrastructure such as small cells.

On April 15, 2019, Rep. Peter A. DeFazio (Oregon) wrote a letter to the FCC and FDA regarding the “thousands of small cell sites in neighborhoods and communities” and specifically asks for: 1. the research used to determine 5G is safe; 2. what gaps there are in the science and; 3. what efforts the federal government has taken to educate the public about its research on RFR and the FCC’s regulatory limits. Representative Thomas Suozzi also sent an April 16, 2019 letter to

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[129] *FCC and FTC Fiscal Year 2019 Budget Requests,* Timemark 1:14:50 | *C-SPAN.Org*. https://www.c-span.org/video/?445704-1/fcc-ftc-leaders-testify-2019-budget-requests. Accessed 13 Dec. 2021.

the FCC requesting the FCC "provide my office and all relevant House Committees with the information used by the FCC, FDA, and other related health agencies to make 5G safety determinations." Representative Andy Kim (New Jersey) sent a March 28, 2019 letter asking about the health effects of the 5G networks.
"What recent, independent scientific studies demonstrate the safety of SG technologies?

1. Has the FCC or any other agency conducted research into potential long-term health outcomes of repeated exposure to radio frequencies similar to those present in high-band 5G cells? If so, what were the results of such study?
2. Have any 5G telecommunications service providers conducted studies into the long-term health outcomes of repeated exposure to radio frequencies similar to those present in high- band 5G cells? If so, what were the results of such study?
3. How are the FCC and 5G service providers working with local governments and municipalities to address citizens' concerns concerning 5G implementation?
4. What procedure exists for residents to file complaints with the FCC regarding the installation of small cell 5G sites in their neighborhoods?"

The elected officials' questions were not responded to with any details and mostly ignored. Instead the FCC sent nearly identical letters responding to Representative Defazio, Representative Thomas Suozzi and Representative Andy Kim on April 30, 2019. All of these letters responded that the FCC "relies on the expertise of health and safety agencies and organizations with respect to appropriate levels of RF exposure" and was engaged in a rulemaking and considering all the evidence on their record. No information was provided on how the issue of 5G cell antennas were being researched for long term exposure. In December 2019 the FCC decided to close their rulemaking largely based on the FDA's determination that RF limits were safe, despite the fact that the FDA has no authority in regards wireless infrastructure such as small cells and had not reviewed the full body of research on 5G technology.

On July 23, 2019, New York State Senator James F. Gaughran wrote the FCC on the "possible detrimental health effects caused by 5G small cells" because " throughout Long Island, 5G small cell towers are being installed in residential neighborhoods in close proximity to houses, schools, and parks…" The Senator requested a study on 5G and to provide his office "with all relevant information used by the Federal Communications Commission to make 4G and 5G small cell tower safety determinations." Scarato called the Senator on October 14, 2021 and was informed that the FDA had not responded, but that Scarato should check to see if Representative Thomas Suozzi had received a response but the only response to Suozzi predates the Gaughran letter.

Documentation that the FDA is misrepresenting that they are reviewing the health effects of 5G.

The FDA has never evaluated the totality of the science to conclude any opinion on the safety of human exposure to 5G technology or cell tower radiation. All the FDA has done is to release a now outdated literature review (ending in 2018) focused solely only on cell phones and cancer. This literature review omits studies on damage to DNA, the brain and reproduction. The FDA literature review is not a systematic review nor is it a risk analysis nor is it an evaluation of FCC cell tower radiation limits, despite being presented in this way.

Further, the FDA has no authority in regards to cell tower radiation and 5G infrastructure. This was confirmed in a January 11, 2022 letter by Ellen Flannery of the Director of the FDA Office of Policy Center for Devices and Radiological Health who wrote that the FDA doesn't regulate cell towers. When asked about the safety of a cell tower outside a California mother's window, she responded, "The FDA does not regulate cell towers or cell tower radiation. Therefore, the FDA has no studies or information on cell towers to provide in response to your questions." Link to FDA Letter.

The FDA stated on June 20, 2016
"We don't have jurisdiction over cellphone towers since those are environmental emitters."

From: Kassiday, Daniel F. H.
Sent: Monday, June 20, 2016 2:36 PM
To: Nambiar, Madhusoodana; Loloei Marsal, Ana; Pastel, Mary; O'Hara, Michael D; McFarland, Scott
Cc: Pirt, Nancy
Subject: RE: FDA Citizens Petition on Cell Phones, Docket # FDA-2013-P-1374

(b)(5) Deliberative Process . We have already considered the NTP study partial result draft which was released. We don't have jurisdiction over cell phone towers since those are environmental emitters.

Daniel Kassiday
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U.S. Food and Drug Administration / Center for Devices and Radiological Health /
Office of In Vitro Diagnostics and Radiological Health / Division of Radiological Health
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Daniel.kassiday@fda.hhs.gov
This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.
For general information about electronic products, please visit the FDA website http://www.fda.gov/Radiation-EmittingProducts/default.htm. For Accession number status, please call (301) 796-6627. For assistance with eSubmitter please write to: esubmitter@fda.hhs.gov. Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received. https://www.research.net/s/cdrhcustomerservice?O=500&D=560&B=564&E=&S=E

The 2021 FDA's Annual report was released on January 31, 2022 and there is no mention of the issue of cell phones or cell towers or wireless electromagnetic radiation. The FDA has not

shown any evidence of monitoring research with new agency reports, meetings or budget on the issue.

A Pittsburgh Law Review article on the FDA and it's role in ensuring public safety in regards to wireless radiation entitled, The FCC Keeps Letting Me Be: Why Radiofrequency Radiation Standards Have Failed to Keep Up With Technology concludes, "The FCC and FDA have failed in their obligation to prescribe safe RFR guidelines produced from wireless communication devices to protect the public health and safety."

In December 2021, numerous groups petitioned the Department of Health and Human Services regarding the issue of radiofrequency radiation exposure requesting it be declared as an Imminent Hazard to public health because while the RF exposures to children and vulnerable populations are rapidly increasing, the FDA has not clarified its present official safety policy. Scientific studies are documenting biological harm at levels far below the current 1996 Federal Communications Commission (FCC) exposure guidelines. The petition documented people harmed by RFR and also the misleading and inaccurate statements by the FDA regarding RFR safety that have resulted in the widespread public belief and reliance by federal agencies and state governments, physicians, and the public that the FDA is ensuring safety.

In their response, the FDA denied the petition, stating that the section of the law on the issue of the FDA and imminent hazard radiofrequency does not apply to cell phones or wireless devices.

Additional Documentation

- The Government Accountability Report on 5G (GAO 2020) clarified that the FDA and other organizations "only reviewed a subset of the relevant research" and stated in regards to the FDA Literature Review that "The assessment focused on cancer-related animal and human studies of frequencies below 6 GHz."
- In 2020, the FDA refused to testify to the New Hampshire State Commission on 5G and refused to answer specific questions regarding it's purported review of health effects of 5G and wireless networks. Although the FDA responded with a few general sentences about how "FDA's doctors, scientists and engineers continually monitor the scientific studies and public health data for evidence that radio frequency energy from cell phones could cause adverse health effects, "the FDA refused to answer specifics such as providing reports or answering questions about the safety margin, and the FDA's research activities. Read FDA Communications with the New Hampshire 5G Commission

The FDA has never publicly released any reports focused on 5G phones nor 5G networks nor shared scientific citations that researched health effects of 5G. The FDA has only performed a limited literature review looking *only at cancer. The literature review* omits research on 5G as well as impacts to the brain, oxidative stress, and reproduction. It omits evaluation of children's unique vulnerability. Most importantly it discounted the results of the National Toxicology Program which is why numerous scientists - including several now retired US government scientists - are calling for the FDA to retract the review as it offers unsubstantiated assurance of safety (EHT 2020).

In the FDA's 2020 Literature Review the word "5G" is absent and none of the studies the FDA reviewed were noted to specifically include 5G modulations. 5G phones will have more antennas than previous generations, including antennas for the millimeter wave networks. Although some 5G networks may use the *same frequencies* as current generations, 5G uses different technical specifications, with more complex modulation patterns and beam characteristics, and the new networks will be a part of the 5G environment that will include billions of "smart" wireless devices—all of which will result in a different biological impact to the public compared to earlier generations of technology[130,131,132,133]. Yet the FDA has not shown any review of the 5G modulation.

Furthermore, the frequencies reviewed by the FDA's 2020 Report were 100 KHz to 6 GHz (as stated on page 9). While it is true that some 5G networks and cell phones will use low- and mid-bands (covered in the frequency range "reviewed" by the FDA), 5G networks and handsets will also utilize higher frequencies that extend past 6 GHz and the FDA has no documentation of reviewing these frequencies. As an example, Verizon's 5G spectrum includes 28 GHz and 39 GHz mmWave bands.

Research studies sent to the FDA by Scarato in an email on June 2, 2018 indicates 5G's higher frequencies are uniquely absorbed into human skin presenting new and different implications compared to the lower frequencies[134,135].

The FDA has never shown reports or documentation of its continued monitoring of research on 5G's complex modulation or higher frequencies, despite asserting that it is doing so.

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[130] Di Ciaula, Agostino. "Towards 5G Communication Systems: Are There Health Implications?" *International Journal of Hygiene and Environmental Health*, vol. 221, no. 3, Apr. 2018, pp. 367–75. *PubMed*, https://doi.org/10.1016/j.ijheh.2018.01.011.
[131] Kostoff, Ronald N., et al. "Adverse Health Effects of 5G Mobile Networking Technology under Real-Life Conditions." *Toxicology Letters*, vol. 323, May 2020, pp. 35–40. *ScienceDirect*, https://doi.org/10.1016/j.toxlet.2020.01.020.
[132] Wojcik, Damian, et al. *Serious Safety Concerns about 5G Wireless Deployment in Australia and New Zealand*. May 2020, pp. 47–54.
[133] Russell, Cindy L. "5 G Wireless Telecommunications Expansion: Public Health and Environmental Implications." *Environmental Research*, vol. 165, Aug. 2018, pp. 484–95. *ScienceDirect*, https://doi.org/10.1016/j.envres.2018.01.016.
[134] Betzalel, Noa, et al. "The Modeling of the Absorbance of Sub-THz Radiation by Human Skin." *IEEE Transactions on Terahertz Science and Technology*, vol. 7, no. 5, Sept. 2017, pp. 521–28. *IEEE Xplore*, https://doi.org/10.1109/TTHZ.2017.2736345.
[135] Betzalel, Noa, et al. "The Human Skin as a Sub-THz Receiver - Does 5G Pose a Danger to It or Not?" *Environmental Research*, vol. 163, May 2018, pp. 208–16. *PubMed*, https://doi.org/10.1016/j.envres.2018.01.032.

The FDA omits to the public and members of Congress that it has no authority in regards to cell towers and 5G small cells and the FDA omits that it has never released any scientific review in regards to cell tower radiation exposure.

While the FDA slips in sentences to elected representatives that it has “not seen credible evidence” regarding “5G handsets”—rather than stating just “5G”, which technically would also include the cell tower and base station antenna networks—most readers and elected officials would be oblivious to the fact that the FDA has not looked robustly at the science on cell tower/base station emissions—the continuous day and night environmental exposures. They do not seem to be aware that the FDA is not tasked to address this issue. The FDA should have clarified to the elected officials that it does not have authority in regards to cell towers, but the FDA did not do this, allowing the reader to assume the FDA has investigated every aspect of the 5G network.

The FDA asserts to the public and elected officials that 5G is safe despite no documentation of any systematic risk assessment for the 5G modulations or the full range of 5G frequencies. If indeed the FDA is reviewing the research on 5G, such a review has not been made public.

Misrepresentation #14: The FDA misrepresents its level of review of the science on cell tower emissions and communicates that cell tower exposures - including “small” cells- are safe.

The FDA has put forward misleading information about its level of review regarding infrastructure- specifically cell towers despite the fact that the FDA has no authority nor role in regards to cell tower or wireless antenna infrastructure. So called “small” cells which are shorter cell towers/wireless facilities are included in this misleading communication.

FAQS about the FDA and cell tower networks:

- The FDA literature review did not review the science on cell tower exposure specifically.
- The FDA literature review did not consider the daily chronic exposure to low level RFR as people would get from cell towers (i.e no quantification of exposures correlated to research studies.)
- The FDA has zero reports evaluating the research on aggregate exposures from cell towers in combination with other personal exposures such as cell phones, Wi-Fi and smart home devices for example.

- The FDAs authority is for consumer electronic devices, not for industrial equipment such as macro cell towers.

Examples of how the FDA is misrepresented as providing proof of safety for cell tower infrastructure includes these examples:

Tucson Arizona Small Cell Information: Under FAQS "When a complaint comes in with health concerns regarding the small cell" the City states "As the City of Tucson does not and cannot, under state and federal law, regulate small cell wireless technology based on health concerns, the following Federal and World Health Organization resources are provided to answer questions" and the FDA website is provided as an example. See https://www.tucsonaz.gov/tdot/small-cell-poles-faqs-and-information

Round Valley Indian Tribe Cell Tower Project: The Round Valley Indian Tribe government website has a page on a cell tower installation featuring three documents from the FDA as proof of safety: The Literature review, the 2019 letter to the FCC and the FDA website page Scientific Evidence for Cell Phone Safety. The page even goes so far as to tout these documents as proof of safety for animals stating *"Owls and bats are known to be in this area next to the Tribal office and church, these are very important animals to our ecosystem...There are no impacts to wildlife when it comes to 4G and so far from the studies, even 5G technologies (please see attached documents* [referring to FDA and other entities] *below)."*
See https://www.rvit.org/about/cell-tower-project

Hempfield School District Cell Tower Information: After "hearing concerns from Hempfield stakeholders regarding the installation of cell towers on school district property" the district put together information including a link to the FDA website. See https://www.hempfieldsd.org/Page/735

In order not to duplicate content, please go to Misrepresentation #13 "The FDA misrepresents its level of review of 5G technology, communicating that the 5G network is safe" for extensive documentation on the way the FDA is inaccurately put forward as providing proof of safety for cell tower networks. 5G networks and cell towers networks are often used interchangeably by members of Congress and the public. The FDA information is misleading and allows elected officials and the public to assume the FDA is ensuring safety and the FDA does nothing to correct this misperception.

VI. The FDA's Critical Omissions

This section lists the FDA's omissions of critical facts regarding the issue of RFR health effects. While some omissions have already been well documented in other sections of this Declaration,

we wanted to reference additional omissions and provide the detail on why they are critical to understanding how this issue is misrepresented by the FDA. This is only a sampling of the FDA's omissions.

Omissions Related to FDA's Role and Authority

4. FDA has only presented activities in relation to electronic devices such as cell phones- not other wireless devices such as routers, laptops, security systems, Wi-Fi, Bluetooth, cell towers etc. However, according to the Food, Drug, and Cosmetic Act the FDA could be addressing all consumer electronic devices, not just cell phones. Yet the FDA seems to have chosen to ignore other devices.
5. FDA omits that it has no authority in regards to telecommunications infrastructure such as cell towers, or 5G/4G "small" cell towers and the FDA has done no science based review on health effects from the cumulative emissions of this equipment.
6. FDA omits that it has no authority nor expertise regarding impacts to wildlife or natural environment (i.e trees, plants) and not reviewed adverse effects to flora and fauna.

Omissions Related to FDA's Level of Review

6. FDA omits it has not shown review of science on non- cancer effects.
7. FDA omits it has not shown review of science in relation to 5G technology.
8. FDA omits it has not performed a public risk analysis of RFR.
9. FDA omits it has not analyzed the FCC limits in relation to the current body of science.
10. FDA omits that no other federal health and safety agency is actively engaged on this issue.

FDA Omits It Has Not Reviewed the Science on Magnetic Fields From Cell Phones Despite Mounting Science Showing Harm.

4. FDA omits that it has authority to regulate both RFR **and magnetic field EMF emissions** from consumer electronic devices according to the Federal Food, Drug, and Cosmetic Act **refers to "electronic product radiation."** However the FDA seems to have chosen only to address RFR emissions and has shown no activities in relation to the scientific review of health effects from magnetic field EMF.
5. FDA omits that it has not reviewed the science on health effects from magnetic field electromagnetic exposure.
6. FDA omits how the public can reduce exposure to magnetic field or ELF EMF.

Omissions Related to FDA's Public Health Information on How To Reduce Exposure

8. FDA omits that hundreds of scientists are warning that FCC limits are not adequate protective and that the public should reduce exposure. Instead FDA downplays science indicating risk and communicates that reducing exposure is not necessary.
9. FDA omits science indicating children and the fetus are more vulnerable as their rapidly developing brains are more sensitive.
10. FDA omits numerous strategies to reduce cellphone radiation exposure and only presents a short list of 4 ways.

11. FDA omits a robust list of sources of RFR exposure- all the ways that people are exposed from cell towers, to video games, to phones to Wi-Fi printers.
12. FDA omits strategies to reduce exposure from wireless, Bluetooth and Wi-Fi devices such as speakers, gaming consoles, Wi-Fi routers and baby monitors.
13. FDA omits that issuing wired internet and telephone connections eliminates RFR exposure.
14. FDA omits reference to scientific research showing adverse effects from exposure.

Omissions Related to FDA's Involvement in the National Toxicology Program

5. FDA omits that the findings of an adverse effect at non thermal exposure levels means that the basis for FCC limits is no longer valid.
6. FDA omits the actual findings of the NTP studies- increased brain and heart tumors, DNA damage and heart damage and also omits the conclusion of "clear evidence of cancer" in male rats.
7. FDA omits that it has known the NTP design for years - to test the assumption that heat is the relevant factor- and yet the FDA has never contacted the NTP to communicate that the animal study the FDA asked or was irrelevant to understanding effect to humans.
8. FDA omits that it did not offer comments during the NTP peer review in March 2018.

FDA Omits that the Radiofrequency Interagency Work Group is defunct and that the FDA's advisory committee- the Technical Electronic Product Radiation Safety Standards Committee has not reviewed the RFR health issues.

3. FDA Omits that the Radiofrequency Interagency Work Group is defunct and quietly removed references off its website.
4. FDA omits that the FDA's advisory committee- the Technical Electronic Product Radiation Safety Standards Committee has not reviewed the RFR nor EMF health issues

Omissions Related to FDA's Role and Authority

Summary: First, the FDA's authority and role is only in regards to radiation from electronic **product** radiation but has never been interpreted to be in regards to cell towers or base station antennas. Further, the FDA has no opinion on wildlife impacts and should when offering safety opinions, should clarify that other agencies need to be contacted.

Second, the FDA is not even doing its job in this regard because as far as we know, the FDA is **only** focusing on cell phones to the neglect of other electronic products such as smart meters, smart watches, smart printers etc. Additionally, in regards to radiation the FDA is not addressing the other types of non ionizing radiation emitted by cell phones and consumer products such as the magnetic fields or extremely low frequency fields in any meaningful way such as risk

assessment, research review etc.) Yet the FDA does not clarify any of this when health and safety information is requested by government officials.

The FDA is only publicly showing activities related to cell phones and radiofrequency radiation but seems to have more broad authority in terms of other electronic devices and other types of non ionizing radiation.

The FDA is empowered by Congress to regulate electronic products that emit radiation through authority from Sections 531 through 542 of the Electronic Product Radiation Control Provisions of the Federal Food, Drug, and Cosmetic Act. Although the FDA does not pre-market review the safety of wireless devices as it does with drugs or medical devices, the agency does say it has authority to take action if mobile phones are shown to emit radiation at a level that is hazardous to the user.

> **The** Electronic Product Radiation Control Provisions of the Federal Food, Drug, and Cosmetic Act's **definition of "Electronic product radiation" is broader than cell phones and RFR.**
>
> "Electronic product radiation" is defined as including "any ionizing or non-ionizing electromagnetic or particulate radiation…"
> "Electronic product" is defined as "Any manufactured or assembled product (or component, part, or accessory of such product) which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation."
>
> **The FDA could take action on electronic products other than cell phones if it was deemed necessary.**
> Under the Electronic Product Radiation Control provision, the FDA Secretary shall:
> " ... by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety. Such standards may include provisions for the testing of such products and the measurement of their electronic product radiation emissions, may require the attachment of warning signs and labels, and may require the provision of instructions for the installation, operation, and use of such products."

The FDA omits that it could address the RFR in other wireless products but it is only (at least publicly) addressing cell phones specifically.

> The FDA states on its website, "The FDA shares regulatory responsibilities for cell phones…" and the FDA only talks about cell phones on its public information page. We have no data showing the FDA has reviewed the safety issue related real world use of to

smart meters, smart watches, smart printers, smart speakers, wireless baby monitors, smart security devices and so forth. As an example, wireless printers and home cordless phone bases have a 20 cm separation distance the user is supposed to maintain so as not to exceed FCC regulatory limits. Yet people are sitting at desks in body contact to wireless printers often located on adjacent desks and they are sleeping next to baby monitor bases. The FDA is not investigating what the actual real world RFR exposures are from the numerous RFR products used by the public in living, educational and work spaces and the FDA is not investigating what the health effects could be from the complex exposure of numerous frequencies day and night.

The FDA omits that it's authority does not extend to cell towers or 5G/4G small cells.

When asked about 5G safety by members of Congress, or in the section on 5G on its website, the FDA should clarify that it has no authority in regards to cell towers. The FDA only has authority regarding cell phones and consumer devices. The FDA should also share that in fact NO federal agency has any funded authority to address the health effects and exposures **of cell towers or small cells.** The EPA was defunded on this issue in 1996 and is not monitoring emissions nor actively researching the issue.

The FDA omits that it's authority and expertise does not extend to impacts to wildlife or the natural environment and that FCC limits are not applicable to flora or fauna.

While this may seem obvious, most people do even think about environmental impacts. When the FDA writes back to Congressmembers about 5G, it would have been critical for the FDA to recommend that the Congressmembers also contact the EPA and Department of Interior and other relevant agencies for an opinion as the FDA opinion is limited to just human health and only cell phones and consumer devices- **but not 5G cell towers.**

A landmark three part **2021 research review** on effects to wildlife published in R*eviews on Environmental Health* by U.S experts including former U.S. Fish and Wildlife senior biologist Albert Manville states current science should trigger urgent regulatory action citing more than 1,200 scientific references which found adverse biological effects to wildlife from even very low intensities of non ionizing radiation with findings of impacts to orientation and migration, reproduction, mating, nest, den building and survivorship (Levitt et al., 2021a, Levitt et al., 2021b, Levitt et al., 2021c).[136] [137] [138]

[136] Levitt, B. Blake, et al. "Effects of Non-Ionizing Electromagnetic Fields on Flora and Fauna, Part 1. Rising Ambient EMF Levels in the Environment." *Reviews on Environmental Health*, May 2021. *PubMed*, https://doi.org/10.1515/reveh-2021-0026.
[137] Levitt, B. Blake, et al. "Effects of Non-Ionizing Electromagnetic Fields on Flora and Fauna, Part 2 Impacts: How Species Interact with Natural and Man-Made EMF." *Reviews on Environmental Health*, July 2021. *PubMed*, https://doi.org/10.1515/reveh-2021-0050.
[138] Levitt, B. Blake, et al. "Effects of Non-Ionizing Electromagnetic Fields on Flora and Fauna, Part 3. Exposure Standards, Public Policy, Laws, and Future Directions." *Reviews on Environmental Health*, De Gruyter, Sept. 2021. *www.degruyter.com*, https://doi.org/10.1515/reveh-2021-0083.

Omissions Related to FDA's Level of Review

- **The FDA omits that it has not done a systematic review or risk assessment of the totality of research on RFR- at least not a systematic review made publicly available and certainly not about 5G.** Further, and as well described in other sections, the FDA has not performed any systematic research review or made publicly available that includes all health endpoints such as oxidative stress, electromagnetic sensitivity, impacts to brain development, and impacts to sperm development.
- **The FDA omits that it has not done a best practice science based evaluation of the adequacy of FCC's human exposure limits. Yet the FDA still offers an opinion regarding these FCC limits.** Further, if indeed a non-public report exists documenting the FDA's review of the limits, then the FDA should clarify if that review is for Maximum Permissible Exposures, Local Exposure and/or Whole Body Exposures. Is the FDA's opinion for occupational exposure limits as well? Is the FDA's opinion for test methods and the metric used to measure RFR exposure- the SAR? At this time the FDA is making large sweeping generalizations and not specifying which aspects of the limits it has supposedly evaluated- if indeed it has evaluated the FCC limits at all. The FDA omits these important aspects when it offers an "opinion" to federal agencies. As members of Congress are not aware of the complexity of the regulations, they do not understand how several issues are omitted and why it is critically important.
- **The FDA has a long history of contradictory communications regarding its level of review on RFR. The description of the FDA's level of review has changed.**

  There are two examples that exemplify the contradictory communications regarding FDAs activities or lack of activities.

  First, years ago in 2004[139] the FDA stated it does *"not review the safety of radiation emitting devices"* and that it recommended research *"into possible biological effects"* but then in 2020 the FDA rewrote this text and now the reader will be unaware of the limited scope of the FDAs activities.

  As you can see below statements were deleted in the 2020 FDA rewrite.

FDA 2004 Webpage	FDA 2020 Webpages
"What is FDA's role concerning the safety of wireless phones? Under the law, **FDA does not review the safety of radiation-emitting consumer products such as wireless phones before they can be sold,** as it does with	FDA Cell Phone Page "The FDA shares regulatory responsibilities for cell phones with the Federal Communications Commission (FCC). Under the law, the FDA is responsible for, among other things:

[139] *Questions and Answers about Wireless Phones*. 3 Feb. 2004, https://web.archive.org/web/20040203144346/http://www.fda.gov/cellphones/qa.html#23.

new drugs or medical devices. However, the agency has authority to take action if wireless phones are shown to emit radiofrequency energy (RF) at a level that is hazardous to the user. In such a case, FDA could require the manufacturers of wireless phones to notify users of the health hazard and to repair, replace or recall the phones so that the hazard no longer exists." Although the existing scientific data do not justify FDA regulatory actions, FDA has urged the wireless phone industry to take a number of steps, including the following: ● Support needed research into possible biological effects of RF of the type emitted by wireless phones; ● Design wireless phones in a way that minimizes any RF exposure to the user that is not necessary for device function; and ● Cooperate in providing users of wireless phones with the best possible information on possible effects of wireless phone use on human health	Consulting with other federal agencies on techniques and programs for testing and evaluating electronic product radiation. For example, the FDA provides scientific input and expertise to the Federal Communications Commission (FCC). The FCC sets limits on the emissions of radio frequency energy by cell phones and similar wireless products. Collecting, analyzing, and making available scientific information on the nature and extent of the hazards and control of electronic product radiation. For example, the FDA provides information for the public about the radio frequency energy emitted by cell phones. FDA Scientific Evidence for Cell Phone Safety Web Page "The FDA's doctors, scientists and engineers continually monitor the scientific studies and public health data for evidence that radio frequency energy from cell phones could cause adverse health effects. If a credible risk is detected, the FDA will work closely with other federal partners to mitigate the risk."

Changes to FDA website from 2004 to 2020 regarding its collaboration with the U.S. National Toxicology Program study on the animal study the FDA itself requested.

FDA 2004 Webpage	FDA Cell Phone Page
"FDA is working with the U.S. National Toxicology Program and with groups of investigators around the world to ensure that high priority animal studies are conducted to address important questions about the effects of	2018 Statement by Dr. Shuren "As scientists, we welcome new studies. Animal studies like this one contribute to our discussions on this topic, but we must remember the study was not designed to test the safety of cell phone use in humans, so we cannot draw conclusions about the risks of cell phone use from it. "

exposure to radiofrequency energy (RF)."	FDA Scientific Evidence for Cell Phone Safety Web Page "The conclusions relating to public health risks reached by the FDA's scientists differ from those of the NTP, and the FDA determination is that the study did not demonstrate that cell phones cause cancer."

FDA Omits It Has Not Reviewed the Science on Magnetic Fields From Cell Phones Despite Mounting Science Showing Harm.

FDA omits that cell phones and wireless devices emit magnetic fields and electric fields in addition to RFR. The FDA has not shown any activity regarding this issue despite the fact that it does have authority to act as magnetic field EMF is a type of radiation emitted from consumer electric products.

In 2001 the International Agency for Research on Cancer concluded that exposure to power-line frequency ELF-EMF is a "possible " human carcinogen- a decision based largely on evidence of an increased risk for childhood leukemias with residential exposure to powerline frequencies. The studies linking magnetic fields to childhood cancer and biological effects have increased since 2001. A 2021 meta-analysis concluded "significant associations were observed between exposure to ELF-MFs and childhood leukemia. Furthermore, a possible dose-response effect was also observed."[140] The United States has no limit on legal levels of magnetic field EMF radiation.

In addition to exposure from power lines and electrical facilities, when people carry phones in close body contact, or laptops on their laps, they are exposed to more intense levels of magnetic fields. Kaiser Permanente research found associations between prenatal exposure to magnetic fields and adverse effects such as miscarriage, ADHD, obesity and asthma.

Yet the FDA has not shown any continuos review of the science regarding these emissions from electronic devices, nor has the FDA posted any information to the public regarding their daily exposure from devices close to the body and how they can reduce exposure.

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[140] Seomun, GyeongAe, et al. "Exposure to Extremely Low-Frequency Magnetic Fields and Childhood Cancer: A Systematic Review and Meta-Analysis." *PLOS ONE*, vol. 16, no. 5, Public Library of Science, May 2021, p. e0251628. *PLoS Journals*, https://doi.org/10.1371/journal.pone.0251628.

Omissions Related to FDA's Public Health Information on How To Reduce Exposure

The FDA downplays the need for the public to reduce cell phone exposure on its web pages. The FDA webpage Reducing Radio Frequency Exposure from Cell Phone Radiation states "there is no established health benefit from reducing an individual's RF exposure from cell phones. Nevertheless, some people still have concerns about RF energy, and there are some simple actions that could help reduce an individual's RF energy exposure from cell phones."

As Dr. Melnick states in his February 27, 2020 letter to the FDA:

> "The message for the general public appears to be that precautionary measures for use of cell phones are not necessary in spite of the fact that numerous studies have provided compelling evidence of increased cancer risk associated with exposure to cell phone RFR. **This is an irresponsible message for a government agency that claims its mission is to protect consumers and promote the public health."**

The FDA omits published research indicating pregnant women, children and babies are more vulnerable to RFR.

As documented earlier in FDA Misrepresentation #10 the FDA webpage is void of information on how children absorb more RFR deeper into their brain and how their brains are more sensitive to RFR. Regarding pregnancy, the FDA has no information at all, not in terms of science nor on limiting exposure- i.e. keeping the phone away from the abdomen.

In contrast to the USA, France has a 2019 Order that recommends reducing cell phone radiation with speakerphones and people are informed when they buy the phone to *"Keep radio equipment away from the belly of pregnant women, and away from the lower abdomen of adolescents."*

The FDA provides only 4 ways to reduce cell phone radiation exposure, omitting <u>numerous additional ways</u> the public could reduce cell phone exposure.

The FDA omits that people can reduce RFR exposure by keeping the phone away from the body- by not carrying phones in a pocket or in a bra. The FDA omits that phones emit even when not in use so people can use airplane mode to reduce RFR. The FDA omits that cell phones can be plugged in to ethernet when needed so antennas can be turned off. The FDA omits that sending or receiving videos and images can substantially increase RFR exposure compared to just texting. The FDA omits information on how to use airplane mode and decrease RFR by turning unused antennas of the phone. In sharp contrast, other groups such as the California Department of Health[141] and American Academy of Pediatrics[142] have put forward robust lists of ways people can

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[141] *CDPH Issues Guidelines on How to Reduce Exposure to Radio Frequency Energy from Cell Phones*. https://www.cdph.ca.gov/Programs/OPA/Pages/NR17-086.aspx. Accessed 13 Dec. 2021.

[142] *Cell Phone Radiation & Children's Health: What Parents Need to Know - HealthyChildren.Org*. https://www.healthychildren.org/English/safety-prevention/all-around/Pages/Cell-Phone-Radiation-Childrens-Health.aspx. Accessed 13 Dec. 2021.

reduce RFR. The American public deserves to know the full range of steps to reduce cell phone radiation exposure.

The FDA fully omits information on exposure sources of RFR <u>other than cell phones</u>.

For example the FDA omits from its public information webpage the fact that people are exposed to RFR from cordless phones and their base stations, tablets, laptops, computers, Wi-Fi routers and hotspots, video game consoles/handsets, baby monitors, mp3 players, signal boosters, security hubs, virtual assistants, wireless peripherals (such as headphones, printer, speakers, keyboard, mouse), wearable wireless tech including "smartwatches and fitness wristbands, "smart" appliances, smart meters, Bluetooth and drones.

The FDA fully omits information on how to reduce exposure to non cell phone RFR exposure exposure sources.

The FDA omits that people can reduce RFR by choosing ethernet internet connections over Wi-Fi, by choosing cords over Bluetooth, by opting for an analog meter over a "smart" meter and wireless and by choosing a corded home phone over a cordless home phone.

The FDA also does not share details on how to reduce RFR from various wireless devices, so for example if you have a Wi-Fi printer you can connect via an ethernet cord or turn the antennas off when not in use etc.

The FDA fully omits information on how to reduce exposure to laptops and computers. The FDA does share how to use an adapter to connect tablets or laptops to ethernet and does not explain that one can turn antennas off in the settings of the device to reduce RFR emissions from the device and work offline.

Omissions Related to FDA's Involvement in the National Toxicology Program

The FDA omits numerous key facts about the NTP study on its webpage which results in a downplaying of the NTP results. All of these omissions result in an uninformed public, media and government.

1. The FDA omits a clear statement about the "clear evidence of cancer" findings of the NTP study in all FDA cell phone radiation website content. Shuren's February 2, 2018 statement and the FDA website page Scientific Evidence for Cell Phone Safety contain no statement that says "Clear evidence of an association with tumors in the hearts of male rats. The tumors were malignant schwannomas." as stated by the NTP. In the FDA statement on the NTP study of November 1, 2018, the FDA does have on the eighth

paragraph a paragraph with the types of tumors listed but the sentence is void of the words “cancer”. Only a very sophisticated member of the public or media will understand what the NTP found from this statement. Further the information on DNA damage and heart damage is fully omitted.

2. The FDA omits a link to the final NTP Reports on its public webpage that discusses the NTP study. Although the webpage was posted in 2020, all that the public will find is a link to the NTP’s February 2018 press release that was superseded by the NTP final reports released in November of 2018. Nowhere on the FDA web page is a link to the NTP webpage on the cell phone cancer study. Even at the bottom of the FDA page under “Scientific Information About Radio Frequency Exposure” other agencies are referenced, **but not the NTP.**
3. The FDA omits that the agency recommended animal studies **in order to gain information regarding human health impacts from long term exposure.** Every agent known to cause cancer in humans also produces this in animals when adequately studied and animal studies have constituted a bedrock of FDA operations for drug development and toxicology evaluation since the agency inception. The FDA is fully aware of why the study was designed with the specific exposure levels as it was to challenge the animals as it is typically done in drug studies. Furthermore the FDA is aware that the study was designed to test the hypothesis that heat is the main harm of RFR and it was not designed to have numerical results that can be directly applicable to human cell phone use.
4. The FDA omits that the FDA has not completed- at least not publicly- a quantitative risk assessment with the NTP data sets to understand what the NTP study actually means in terms of human health risks.
5. Although the FDA webpage states the NTP study was conducted at the request of the FDA” the NTP does not provide a link to the nomination. The nomination would be illuminating to the American public because despite the FDA's the nomination states:

> “There is currently insufficient scientific basis for concluding either that wireless communication technologies are safe or that they pose a risk to millions of users. A significant research effort, involving large well-planned animal experiments is needed to provide the basis to assess the risk to human health of wireless communications devices.”
>
> “A large number of biological effects have been reported in cell cultures and in animals, often in response to exposure to relatively low-level fields, which are not well established but which may have health implications and are, hence, the subject of ongoing research. It is not scientifically possible to guarantee those non-thermal levels of microwave radiation, which do not cause deleterious effects for relatively short exposures, will not cause long-term adverse health effects.”
>
> “As noted above, the existing exposure guidelines are based entirely on protection from acute injury from thermal effects of RF exposure, and may not be protective against any non-thermal effects of chronic exposures.”

The FDA omits in its public website that research studies have indeed associated cell phones with brain cancer, as well as other effects.

As an example, if you go to the FDA webpage on scientific evidence and search the word "cancer" for example, the word only appears in the context of how cancer rates have supposedly not increased. The page does even explain that numerous studies do in fact link cell phone use to cancer.

The FDA states only:
"In 2013, the International Agency for Research on Cancer (IARC) published a monograph that classified radio frequency fields as possibly carcinogenic to humans (class 2B). This classification is an indication that more research is probably justified. *The 2013 IARC classification was based on limited evidence in humans which were from a few case-control epidemiological studies."*
From this quote, most people will think the IARC classification means "more research needs to be done" rather than understanding that studies even exist showing harm.[143]

FDA Omits that the Radiofrequency Interagency Work Group is defunct and that the FDA's advisory committee- the Technical Electronic Product Radiation Safety Standards Committee has not reviewed the RFR health issues.

The FDA omits that both its electronic product advisory group - the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC)- and the federal Radiofrequency Interagency Work Group (RFIAWG) have never reviewed the issue of health effects. Further, the interagency group is defunct and the technical committee has 9 vacancies. These omissions allow the false illusion to proliferate that the FDA is collaborating with other federal agencies on its RFR activities- providing some oversight- and that there is an advisory committee that provides expert recommendations. The FDA should clarify that the RFIAWG is **no longer active** and that the TEPRSSC has numerous vacancies and has not substantially considered the health issues.

Radiofrequency Interagency Work Group (RFIAWG)

Over the years, the FDA has repeatedly referenced the radiofrequency interagency workgroup (RFIAWG) on radiofrequency radiation. The FDA long stated on it's website that the "*FDA belongs to the Radiofrequency Interagency Work Group. The federal agencies in this group*

[143] IARC. *Non-Ionizing Radiation, Part 2: Radiofrequency Electromagnetic Fields. publications.iarc.fr*, https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Non-ionizing-Radiation-Part-2-Radiofrequency-Electromagnetic-Fields-2013. Accessed 13 Dec. 2021.

have responsibility for different aspects of RF safety and work to ensure coordinated efforts at the federal level." -FDA website "Cell phones" as of December 14, 2019

Webpage archive shows the RFIAWG on the FDA website January 2012, Feb 14, 2015 , January 25, 2018 and April 23, 2019 but not in 2020. Note, even when it was active the RFIAWG never did any systematic research review. Their phone meetings were supposedly every two months but there is no agenda nor meeting notes available.

However because the FDA omits that the group is all but defunct, officials scientists and federal agencies still believe it exists.

The FDA should clarify on its website and to Congress and government agencies that this group no longer meets and that there is effectively no interagency collaboration. Because the FDA has omitted these facts, other agencies **still reference the RFIWG** and mislead the public, thinking there is collaboration and oversight regarding RFR health effects.

Examples of how the FDA's omission impacts the perception of FDA's activities- the false illusion that it is collaborating with other federal agencies in a group actively in bestigating RFR. The FDA should release a memo clarifying that they are not active in the RFIAWG.

1. **The FCC webpage:** As of the writing of this document on November 1, 2021, the FCC has on its webpage "RF Safety FAQs" a reference to the RFIWG stating:
   "For example, the EPA chairs a Radiofrequency Interagency Working Group, which coordinates RF health-related activities among the various federal agencies with health or regulatory responsibilities in this area."

2. **Locality uses FCC web page information:** As an example of how the misleading information mushrooms out- the FCC Safety FAQs were placed on the record of the April 24, 2018 Sebastopol California Planning Commission Meeting. So now elected officials of a local government are provided inaccurate information.

3. **Policy decision rests on the FDA determination and assumes if there is a future problem the RFIAWG would let them know.** The National Highway Traffic Safety Administration 49 CFR Part 571 [Docket No. NHTSA-2016-0126] Federal Motor Vehicle Safety Standards; V2V Communications states that the "continued efforts" of the RFIAWG would provide future guidance. "The FDA found that most studies conducted to date show no connection between certain health problems and exposure to radiofrequency fields via cell phone use and that attempts to replicate and confirm the few studies that did show a connection have failed… We will continue to monitor the progress of this issue and closely follow the efforts of the Radiofrequency Interagency Work Group (RFIAWG) which may yield any potential future guidance for wireless device deployment and usage."

4. **Industry consultant presents the existence of interagency workgroup to health and safety committee of City:** Industry consultant Jerrold Bushberg presented an "Introduction to Potential Health Considerations of 5G Networks" at the Beverly Hills California Health and Safety Commission Meeting on February 24, 2020 and referenced the RFIWG *despite the fact that it is defunct* (See Agenda, Watch video, See full transcript).

   "The NCRP has not been asked to update the report since it was issued and that is the job of the federal agency working group for safety surveillance. Their members include individuals from the EPA, NIOSH, OSHA and the FCC and this group meets six times a year. Primarily just to review what is going on around the world and they go to meetings and ask the question whether they think the standards in the US are still reasonable and in-line with what is happening around the world."

CITY OF BEVERLY HILLS
455 NORTH REXFORD DRIVE, BEVERLY HILLS, CA 90210
Federal Interagency Agency Working Group (RF Safety Surveillance)
Environmental Protection Agency: (EPA)
Food and Drug Administrati DA)
National Institute of Occupati Health & Safety (NIOSH)
Occupational Health and Safety Administration (OSHA)
Federal Communication Commission (FCC)
This Group meets/teleconference 6 times per year
1:08:53 / 2:31:45
CC
Health and Safety Commission Meeting

Notable Information About the RFIAWG

1997: On May 5, 1997 the FDA wrote then Representative Edward J. Markey a letter stating that, "As a result of the oversight briefing with the Subcommittee you chaired in February 1993, the Environmental Protection Agency (EPA), together with CDRH, the National Institute for

Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), the Federal Communications Commission (FCC), and the National Telecommunications Information Agency (NTIA) reconstituted a Radiofrequency Interagency Work Group (RFIAWG) in August 1994 to coordinated issues of concern to these agencies, including monitoring RFR from wireless communication. This group has been instrumental in providing a coordinated Federal response to industry's research as recommended in the 1994 GAO Report entitled, "Status of Research on the Safety of Cellular Phones." and “A significant research effort, involving exposures of large numbers of animals to the various types of cellular phone modulation in current on expected use, coupled with epidemiological surveillance of exposed populations, is needed to provide a further basis for risk assessment of these devices.”

1999: US Radio Frequency Interagency Workgroup (RFIW) Letter to Richard Tell Chair, IEEE SCC28 (SC4) Risk Assessment Work Group on Critical Concerns About RF guidelines.

In this letter, members of the RFIAWG of which the FDA was a member- identify several critical issues with the RF exposure guidelines. Their concerns include the need for a biological basis for SAR limit and they point out that the limits for brain and bone marrow should be lower than those from muscles and fat as tissues are not equally sensitive. They question the selection criteria for the adverse effect and state there is extensive data on acute effects but that the lower-level non-thermal chronic exposure effects may be very different and chronic effects need to be accounted for. They state the uncertainties in the data should be addressed. “These studies have resulted in concern that exposure guidelines based on thermal effects, and using information and concepts (time-averaged dosimetry, uncertainty factors) that mask any differences between intensity-modulated RF radiation exposure and CW exposure, do not directly address public exposures, and therefore may not adequately protect the public.” Read the 1999 Federal Radio -Frequency Interagency Workgroup (RFIW) Letter to Richard Tell

2002: The United States Radio Frequency Interagency Workgroup’s (RFIWG) Letter to CK Chou on Additional Concerns about US RF Exposure Guidelines.

EPA’s Norbert Hankin penned the federal RFIWG’s second letter - of which the FDA’s Adiy Desta was a member- on concerns about RF human exposure guidelines with three additional issues.; the sensitivity of different tissues to temperature; that a relaxation of standards will allow for higher exposures; and that the pinna- or ear- is being considered an extremity and will be allowed far higher RF limits without considerations of different body sizes.

Read the 2003 Interagency Radio Frequency Workgroup’s Letter to CK Chou on RF Exposures.
To our knowledge neither the 2003 or 1999 letters were ever responded to. We also do not if the FDA followed up on these issues the group raised. These issues are very important to understanding bioeffects.

2013: According to a GAO report the FDA communicated that the group was still active:

> *“Radiofrequency Interagency Work Group. FDA commented that they exchange information with FCC on the current state of research, standards activity, and health*

effects of cell phone radiation and that most interactions are facilitated by FDA and FCC participation in the Radiofrequency Interagency Working Group. For example, FDA worked on the interference between consumer products and active medical implants, such as the interference between MP3 players and pacemakers. FDA responded that they have worked collaboratively (with FCC) to develop communications on wireless devices. According to FDA's website, the federal agencies in the working group include NIOSH, EPA, FCC, OSHA, and the National Telecommunications and Information Administration. The website also states that the federal agencies in this workgroup have responsibility for different aspects of radiofrequency safety and work to coordinate efforts at the federal level. Additionally, FCC staff told us that the working group meets every 2 months to share information. For instance, one topic discussed has been the development and eventual adoption of the FCC notice of inquiry regarding the propriety of its current radiofrequency emissions limits."

2018: A March 2018 Public Integrity article "Residents Worried about Small Cell Safety Have Been Waiting Years For Federal Guidance" stated that, "One of the groups the FCC says it relies on is a nine-member committee called the Radiofrequency Interagency Work Group. The panel is made up of members from mostly federal health agencies — the EPA, FDA, OSHA, NIOSH, the Centers for Disease Control and Prevention, the National Cancer Institute and the National Institute of Environmental Sciences, according to the EPA...An EPA spokesperson, however, described the interagency group, which first met in 1995, as an "informal forum" that doesn't have a scheduled meeting time, nor an official chairman and is not mandated to research radio-frequency standards."

2020: Lee Ann B. Veal, Director of the Radiation Protection Division, U.S. Environmental Protection Agency wrote Theodora Scarato that the group had not met in years.

> **Theodora Scarato:** "Please send me the staff member of your respective agency who is on the Interagency Radiofrequency Workgroup as I have repeatedly tried to get this information and it is never provided to me."
>
> **EPA Response:** The Radiofrequency Interagency Work Group (RFIAWG) is an informal forum for exchange of information and the group does not meet to set, or advise on, policy, rulemaking or guidance. The group has not met in more than two years." Read the full letter from the EPA to Scarato here.

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC)

The TEPRSSC "advises FDA regarding proposed performance standards for electronic products which emit radiation." However the **TEPRSSC has not been active on this issue.**

- **Major Vacancies:** They have 9 vacancies and have not met since 2016 according to the website. TEPRSSC consists of 15 members, five representatives of regulated industry, five of the government (Federal, State, or local), and five of the general public, one of

whom must be a representative of organized labor. Members must be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety.

- **No meetings since 2016**: They have not met since 2016 and never reviewed the issue of health effects of RFR to make any determinations. Documentation of this can be found at Past Meeting Materials, Technical Electronic Product Radiation Safety Standards Committee.
- FCC 2021 Letter to Court in EHT et al. to the FCC includes Charter of FDA TEPRSSC and states that "as the FDA's website discloses, the Committee last met on October 25 and 26, 2016".
- **The FDA is well aware that TEPRSSC is inactive and has vacancies:** In fact, during the oral arguments for Environmental Health Trust et al., v. the FCC on January 25, 2021 the TEPRSSC was brought up by the judge to the FCC lawyer. The judge was asking if the TEPRSSC had reviewed the record as the FDA had not shown that its advisory committees had been called upon to offer an opinion. A day earlier the TEPRSSC page was out of date and the webspage listed members who were no longer in the committee (See way back machine for TEPRSSC Members January 22, 2021) However, On January 25, the FDA webpage was updated that day during the oral arguments which seems to indicate the FDA was was following the EHT et al. v FCC case closely, and realized it should update the website.

VII. The FDA's Lack of Transparency and Refusal to Fully Respond to Questions and the Call for Corrections by the Public, Federal Officials and Scientists.

The FDA refuses to respond to pointed questions directly addressing the FDA's level of review. Examples of letters the FDA has not responded to include:

- **The New Hampshire State Commission on 5G:** When the New Hampshire Commission on 5G wrote to the FDA with several questions, the FDA responded without directly addressing the questions and instead presented a cursory opinion in just a few paragraphs. When the Commission wrote the FDA back asking for answers to specific questions, they did not receive an adequate response, but instead were sent a few paragraphs directing the Commission to the FDA's website.
- **The FDA did not respond to the scientists' letters requesting corrections to the FDA Literature Review and FDA 2020 website changes.**
  The letters the FDA ignored are listed in this document in the section The FDA's 2020 Literature Review contained numerous critical errors that remain uncorrected.

February 27, 2020 Letters Sent to the FDA by Scientists Calling For a Retraction of the Literature Review. Main EHT page detailing the Scientists's Letters to the FDA

- Letter calling for a retraction signed by numerous scientists.
- Ronald Melnick PhD's letter to the FDA on the National Toxicology Program study
- Albert Manville PhD, retired Senior Wildlife Biologist, Division of Migratory Bird Management, U.S. Fish & Wildlife Service, Senior Lecturer, Johns Hopkins University
- Prof. Tom Butler of the University College in Cork, Ireland's letter to the FDA
- Igor Belyaev, PhD, Dr. Sc. Head, Department of Radiobiology of the Cancer Research Institute, Biomedical Research Center of the Slovak Academy of Science
- Paul Heroux PhD, McGill University
- Alfonso Balmori, BSc
- PDF of all letters and statements

- **The FDA's One Senace Response to Scientists**: In response to numerous scientific letters by experts such as 28 year NIH scientist Dr. Ronald Melnick, FDA's Dr. Jeffrey Shuren responded in a March 24, 2020 letter to Theodora Scarato with one sentence *"thank you for sharing your and your colleagues' concerns with. We appreciate your feedback."*
- **Senator Tammy Baldwin:** When the Office of Senator Tammy Baldwin wrote the FDA with specific questions (See September 8, 2020 letter from FDA to Senator Tammy Baldwin, the FDA did not respond to the questions but instead wrote back that:

  > "The Food and Drug Administration (FDA or the Agency) has recently publicly released a considerable amount of information that details the evaluation of scientific evidence related to the safety of cell phone handsets. Specifically, the Agency has conducted and published a detailed literature review of all scientific evidence that has become available for over the past decade, and updated our webpages related to all aspects of radiofrequency radiation from cellphones. Based on this extensive risk analysis, our determination remains consistent that there is no scientific evidence that warrants a change in cell phone safety limits, and that there is insufficient evidence to demonstrate a causal link between cell phones and cancer in the population. We believe that all of the questions contained in your constituent's letter are answered in the publicly available information, and I have included links below to the relevant information.
  > The Agency will, of course, take these comments into consideration as we continue to monitor all available relevant information. Thank you for contacting us concerning this matter. If we may be of further assistance, please let us know."

Theodora Scarato has repeatedly written to the FDA asking for answers to follow up questions from her years of emails with new questions related to the FDA's determination of a safety factor and level of review of the science.
See the questions here in Scarato email communications to the FDA .

Examples of questions that remain unanswered include:

- In light of the French ANFR tests showing excess radiation from phones at body contact, what steps is the FDA taking to address the fact that cell phones and wireless devices have SARS that exceed FCC limits when devices are placed at body contact?
- Please explain why the FDA believes there is a safety factor. As the Chicago Tribune tests indicate, the localized SARs could be at levels that exceed 6 W/kg (the highests SAR in the NTP) when the phone is at body contact. Please also explain why the FDA is not considering that the NTP exposure levels were comparable to localized public SAR limits and all of them were within occupational localized SAR limits.
- We would like to know why the FDA has not taken action to inform the public about the separation distances in light of this published analysis. We also would like to know if the FDA has a specific SAR level that will trigger a FDA action as the FDA has been aware of SAR violations for years.
- Will there be any premarket safety testing for 5G technology? To understand the long term effect on human health? If so please detail the research and who is performing it.
- When did the FDA do a systematic review of the scientific evidence to evaluate impacts on human health?
- The DNA and tumor findings of the NTP indicate non thermal effects from long term exposure as the animals were exposed at levels considered "non thermal. " What is the process by which the FDA is going to integrate this information into an opinion of the safety of exposure limits for RFR both occupational and for the public ?

Years ago the FDA would state its activities. For example in 2004 the FDA website reads:

> ***What is FDA doing to find out more about the possible health effects of wireless phone RF?***
>
> - *FDA is working with the U.S. National Toxicology Program and with groups of investigators around the world to ensure that high priority animal studies are conducted to address important questions about the effects of exposure to radiofrequency energy (RF)*.**[Note today the FDA has rejected the NTP study it asked for]**
> - *FDA has been a leading participant in the World Health Organization International Electromagnetic Fields (EMF) Project since its inception in 1996. An influential result of this work has been the development of a detailed agenda of research needs that has driven the establishment of new research programs around the world. The Project has also helped develop a series of public information documents on EMF issues.* **[Yet today the FDA has shown no involvement with the WHO. In fact the WHO has launched a series of systematic reviews and FDA staff was not represented on any of the papers detailing the study design.]**
> - *FDA and the Cellular Telecommunications & Internet Association (CTIA) have a formal Cooperative Research and Development Agreement (CRADA) to do research on wireless phone safety. FDA provides the scientific oversight,*

obtaining input from experts in government, industry, and academic organizations. CTIA-funded research is conducted through contracts to independent investigators. The initial research will include both laboratory studies and studies of wireless phone users. The CRADA will also include a broad assessment **[the National Academy of Sciences National Research Council Report]** *of additional research needs in the context of the latest research developments around the world.* **[We do not believe this is active in any way at this time now nearly two decades later. The National Academy of Sciences National Research Council Report "The Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communications Devices" documented critical research gaps and called for the need to increase understanding of any adverse effects of long term chronic exposure to RF/microwave energy on children and pregnant women]**

VII. The FDA Website 2020 Rewrite Misrepresents the FDA's Role After A Decade of Stagnant Website Material

Theodora Scarato has been following the FDA website for years. The FDA has significantly altered what it presents as the FDA's role and activities over the years in a haphazard way. The law under which the FDA has authority regarding cell phones has not changed but the FDA's presentation of its activities related to interagency collaboration, scientific review and consumer information has changed.

The FDA website changes are relevant because they exemplify the FDA's lack of consistency regarding its activities.

Here are just a few examples of the inconsistency and omissions on the FDA website over the years.

2009-2019: No FDA website updates for a decade: There was a ten year period of no website updates between 2009 and 2019, except a few sentences about the WHO Class 2 B possible carcinogen determination and - very briefly- the Interphone study results.

Previous to 2009, the webpage had lengthy question/answers and the FDA even referenced research studies that found adverse effects in 2002. Starting in 2015, Theodora Scarato repeatedly wrote to the FDA regarding the website requesting corrections and updates to the incorrect presentation of the findings. The FDA staff never updated the site. However in 2021,

the site was completely updated with fresh new content proclaiming “cell phone safety.” The only study referenced was the NTP study yet the actual findings of that study- increased tumors in the heart and brain- *were never presented.* Instead the FDA only posted text criticising the study.

2019: The FDA removed text stating that the FDA does not review the safety of cell phones before they come to market and replaced it with text about how the FDA is responsible for consulting with other federal agencies like the FCC and collecting and presenting information to the public. These changes create the illusion that the FDA is reviewing the safety of these devices by omitting facts about FDA’s activities in regards to cell phones.

During the decade of no changes (between 2009 and 2019) the main FDA website on cellphones page clarified that the FDA does not do premarket safety testing stating::

> *“Under the law, FDA does not review the safety of radiation-emitting consumer products such as cell phones and similar wireless devices before they can be sold, as it does with new drugs or medical devices. However, FDA does have the authority to take action if cell phones are shown to emit radiofrequency energy (RF) at a level that is hazardous to the user. In such a case, FDA could require cell phone manufacturers to notify users of the health hazard and to repair, replace or recall the phones so that the hazard no longer exists.*

The 2021 update deleted text and replaced it with new text that makes it seem like the FDA is, in fact, quite responsible for safety. The FDA’s new text reads:

“The FDA shares regulatory responsibilities for cell phones with the Federal Communications Commission (FCC). Under the law, the FDA is responsible for, among other things:

- *Consulting with other federal agencies on techniques and programs for testing and evaluating electronic product radiation.*
    - *For example, the FDA provides scientific input and expertise to the Federal Communications Commission (FCC). The FCC sets limits on the emissions of radio frequency energy by cell phones and similar wireless products.*
- *Collecting, analyzing, and making available scientific information on the nature and extent of the hazards and control of electronic product radiation.*
    - *For example, the FDA provides information for the public about the radio frequency energy emitted by cell phones.”*

2019: The FDA removed text referencing the FDA collaboration in the U.S. federal Interagency workgroup RFIAWG and internationally.

Between 2009 and 2019 the FDA website stated:

> **Interagency Working Group**

FDA belongs to the Radiofrequency Interagency Work Group. The federal agencies in this group have responsibility for different aspects of RF safety and work to ensure coordinated efforts at the federal level. The other agencies in this group are:

- *National Institute for Occupational Safety and Health*
- *Environmental Protection Agency*
- *Federal Communications Commission*
- *Occupational Safety and Health Administration*
- *National Telecommunications and Information Administration*

International Workgroup

For the past several years, delegations from Japan, Korea, the European Union, Australia, China, the World Health Organization, and the United States have met to discuss health concerns for wireless telecommunications. The purpose of these workshops has been to discuss scientific issues related to RF exposure from wireless communications technology from an international perspective. Specific topics addressed have included:

- *health effects of emerging wireless technologies*
- *recent biological research*
- *standards development*
- *prospects for international collaboration related to the safety of wireless telecommunication devices.*

The 2021 update deleted the information about the Radiofrequency Interagency WorkGroup and the International Workgroup. The FDA never posted a note or sent out a memo that the Interagency Workgroup was defunct.

2021: The FDA now references the opinion of the National Cancer Institute (NCI) and American Cancer Society (ACS) despite the fact that neither the NCI nor ACS have systematically researched the science to develop a safety opinion.

The 2021 Radio Frequency Radiation and Cell Phones states:

> *"As stated by the National Cancer Institute, "there is currently no consistent evidence that non-ionizing radiation increases cancer risk in humans. The only consistently recognized biological effect of radiofrequency radiation in humans is heating."*

Why the FDA would reference the NCI as the authority?

First the NCI has not reviewed the full body of evidence as clearly stated in its letter to the New Hampshire State Commission on 5G and second, the FDA itself presented a statement of opinion to the FCC regarding the scientific evidence so why doesn't the FDA link to itself?

VIII. The Nationwide Impact of the FDA's Misrepresentations, Omissions and Lack of Transparency is Serious and Deleterious

The FDA's misinformation has influenced the public, media, medical professionals, legal decisions and governments and agencies at local, state and federal levels with serious consequences. Government officials are relying on the FDA information in their opinions and reports which in turn leads to non protective policy. Most importantly the US FCC is relying on the FDA in its inquiry into RFR exposure limits.

Laws have been and are being passed to fasttrack 5G and cell tower networks by stripping local authority. Laws that would inform the public about cell phone radiation exposure are not being implemented.

Members of the public who contact their government officials have their health issues either dismissed or fully ignored. Public health agencies are not warning the public. As a result of the FDA's actions, whenever people raise the issue of health regarding a 5G cell tower in front of their home or Wi-Fi in school or a cell phone to their head, they are told that it meets FCC RFR limits for human exposure and that the exposure is safe.

Medical professionals, school superintendents and the industry itself utilizes the FDA's information to promote the message that wireless radiation is safe and that the NTP study is irrelevant to human health. The public is then uninformed and believes that cell phones and wireless are safe and considers scientists who are experts in the field of RFR and ringing the alarm bell as "fringe".

Thus, the public continues to purchase and use more and more wireless devices unaware of the serious health risks posed by years of chronic exposure.

1. Influence at the Local Level and to Local Governments
2. Influence to State Government and State Elected Officials
3. Influence at the Federal Level to Federal Agencies and Federal Policy
4. Influence to Congress
5. Influence to Members of the Armed Forces
6. Influence to Medical Organizations and Professional Organizations
7. Influence to Lawsuits and The Courts' Perceptions of Safety
8. Influence to the Media
9. Influence to the Wireless Companies' Ability to Promote the Safety of Their Products

10. Influence to the Public Perception of Safety

The FDA's Misinformation Influences at the Local Level and to Local Governments

The FDA websites are used as proof of safety at the local municipal level when the issue of cell phone, cell tower and wireless safety is raised.

NewYork City references the FDA multiple times in their materials on 5G using the agency to substantiate their safety claims.

> LinkNYC Fact vs Myth states: "5G is safe. Thousands of peer-reviewed studies supported by organizations like the U.S. Food and Drug Administration and the World Health Organization have found no negative impact on our health or the environment from wireless devices and cellular networks - like 5G - that utilize radio frequencies."

> LinkNYC5G One pager states, Decades of research by the international scientific community shows radio frequency energy from wireless devices and networks, including 5G, has no negative effects on our health. The evidence includes thousands of peer reviewed studies conducted by the FDA, the World Health Organization, and the FCC.

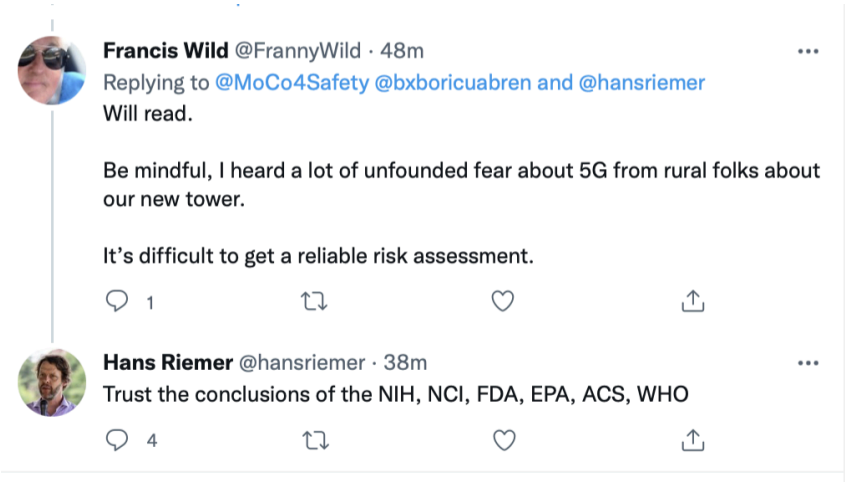
Montgomery County Councilman Hans Riemer, who pushed legislation allowing 5G cell antennas" at 30 from homes and schools without routine notice of public hearing- a common type of industry friendly policy being financed in local municipalities- repeatedly discussed how federal agencies had reviewed the science and determined 5G cell towers were safe- reiterating FDA's misinformation in tweets, facebook posts, statements during Council meetings and newsletters to his constituents.

As an example, Councilman Riemers July 28, 2021 newsletter reads:

> **"What do leading public health authorities say about cell phones and 5G?**
> Safety comes first. Fortunately, the science on wireless waves is compelling. The leading national and international scientific institutes continue to find that cell phones are not linked to health problems. The FDA, which we are proud to have located here, reviews the existing studies and puts them all into a balance. The FDA clearly says, the "weight of scientific evidence has not linked cell phones with any health problems."

As another example, a July 14, 2021 tweet by Councilman Hans Riemer proclaims that “These entities review all the research in order to protect public health.” Not only is the FDA featured despite the fact that it has not done a systematic research review, but furthermore, none of the agencies that Riemer lists has actually ever done a systematic review of all the research- ever.

When asked about cell tower safety, a July 18, 2022 tweet by Councilman Hans Riemer states, “ Trust the conclusions of the NIH, NCI, FDA, EPA, ACS, WHO.”


Francis Wild @FrannyWild · 48m
Replying to @MoCo4Safety @bxboricuabren and @hansriemer
Will read.
Be mindful, I heard a lot of unfounded fear about 5G from rural folks about our new tower.
It’s difficult to get a reliable risk assessment.
1
Hans Riemer @hansriemer · 38m
Trust the conclusions of the NIH, NCI, FDA, EPA, ACS, WHO
4

As another example, when parents raised the health issue in Montgomery County Schools, the school district released a web page where the FDA was listed as performing a 2013 research review which concluded that:

> *“Studies on biological changes were not replicated. No evidence for health problems in adults, children and teenagers.”*

Parents repeatedly wrote the school to correct this false statement as there had been no review and even sent the school district emails from the FDA itself confirming the county website statement on the FDA was inaccurate, but the statement still has not been corrected. It remains online to this day.

New York City Office of Technology posted "Health and safety" information regarding their 5G pole installations which directly links to the FCC website which posts FDA information to substantiate its safety determinations, despite the fact that the FDA has not review the science on 5G or the exposure and health effects of these 5G poles which would include 5 commercial carriers. The New York City website states:

> *"The federal government regulates radio emissions as they relate to health or environmental concerns and constrains local governments from doing more. Read the FCC's guidance and more information about wireless devices and health concerns."*

The FCC page NYC links to states:

> *"Many federal agencies have considered the important issue of determining safe levels of exposure to radiofrequency (RF) energy. In addition to the Federal Communications Commission, federal health and safety agencies such as the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) have been actively involved in monitoring and investigating issues related to RF exposure. For example, the FDA has issued guidelines for safe RF emission levels from microwave ovens, has reviewed scientific literature of relevance to RF exposure (see fda.gov/media/135043/download), and continues to monitor exposure issues related to the use of certain RF devices such as cell phones. Likewise, NIOSH conducts investigations and health hazard assessments related to occupational RF exposure."*

A City of Bowie Maryland Briefing Document for a cell tower at Benjamin Tasker School included a section called Wireless Safety Overview on page 40 citing the FCC as relying on input from the FDA and featuring the FDA logo. First, the FDA is not tasked to ensure the safety of cell towers, but here is one of many examples of the FDA being referenced in regards to cell tower safety.

The FDA pages were cited by Lenox Massachusetts Housing Authority as authoritative information related to "the safety" of cell antennas that were proposed on the building.

The inaccurate presentation of federal agencies is repeatedly presented to Towns by Wireless affiliated companies. In October 2022, Davis Maxton of David Maxson of isotrope wrote to Gwen Miller, Town Land Use Director of Lenox stating, "I rely on the impartial, expert analyses produced by and for respected public health agencies. I encourage the town to continue to do the same.…The town will continue to be asked to ignore the established science as read by competent, expert public health agencies and favor sanctimonious pronouncements by well-read individuals posing under a veneer of impartiality and expertise."

A Tuscan Arizona News 13 report on people concerned about 5G cell towers in their neighborhoods cites the FDA as a source of safety information for cell towers.

> *"According to the FDA, there is no consistent or credible evidence of health problems caused by the exposure to radio frequency energy emitted by cell phones or towers."*

The FDA's Misinformation Influences State Health Agencies and State Elected Officials

State officials also depend on the FDA for information to inform their policy decisions, and they also disseminate the FDA's erroneous safety message in public communiques. The FDA's name and "conclusions" are used on state public health materials promoting the illusion that cell phones and wireless networks are safe.

The Chief Information Officer, Information Technology Division of the School District of Palm Beach County states a myth propagated by the FDA misrepresentation to the FCC in an August 17, 2021 letter that: *"National health agencies have credibly concluded that no adverse health effects have been demonstrated at radio frequency exposures that fall within established safety guidelines—and the exposures from Wi-Fi fall well below those limits."*

The Virginia Department of Health issued a March 12, 2020 release that states, "FDA review finds no link between cell phones and cancer."

Pennsylvania State Representative Mark M. Gillen wrote a letter to a concerned constituent stating that:

> "The FCC also consulted federal health and safety organizations such as the Food and Drug Administration (FDA), the Environmental Protection Agency, the Occupational Safety and Health Administration, and the National Institute for Occupational Safety and Health to develop "consensus" regulations. Together, these bodies have assessed thousands of scientific studies concerning possible health effects of nonionizing radiation. All small cells installed in the United States comply with the FCC's RF guidelines. If you feel that the FCC's RF guidelines are insufficient, you may wish to contact the FCC or your U.S. Congressman and U.S. Senators, since this is within their area of jurisdiction."
>
> …Dr. Swanson testified that the technology used in small cells is more than 30,000 times below the ionizing threshold and 500 times lower than the FCC limit. His statements are supported by the FDA, the National Cancer Institute, the American Cancer Institute and the World Health Organization. Also, the Institute of Electrical and Electronics Engineers' International Committee on Electromagnetic Safety has long held that "the weight of scientific evidence supports the conclusion that there is no measurable risk associated with RF exposures" even at levels five times higher than that permitted by the FCC. "

The Oregon Health Authority (OHA) released a 2020 Report on Wireless and Health referencing statements in the FDA's Literature Review that dismiss science showing harm. The OHA Report

concludes there is insufficient evidence that wireless is harmful and states that its conclusion *"is in line with conclusions on RFR exposures and health by the U.S. Food and Drug Administration…."*

Furthermore OHA also posted a list of resources for the public which has a section of FDA resources. There is a link called "Weight of evidence evaluation of studies on radiofrequency radiation and cancer" to the FDA literature review- which is of course NOT a weight of evidence evaluation as no where in the entire FDA document do they grade or rate each study to properly weigh the evidence. Thus, the Oregon Health Authority now perpetuates the myth that the FDA "weighed" the evidence. As an additional example of the convoluted way the FDAs misleading information is amplified, the OHA also links to the "Health Physics Society (HPA) Factsheet On cell phones, non-ionizing radiation and 5G technology" which references the FDA stating:

> *"In the US, RF exposures are regulated by the Federal Communications Commission (FCC). Current FCC limits date to 1996 (FCC 1997), but in August of 2019, the FCC issued a press release stating that it intends to maintain its current RF exposure safety standards, citing a statement from the director of the US Food and Drug Administration Center for Devices and Radiological Health that the "available scientific evidence to date does not support adverse health effects in humans due to exposures at or under the current limits . . . ." (FCC 2019).*

As another example, the Hawaii State Department of Health has a 5G Factsheet, "What You Need to Know About Radiofrequency Energy and 5G cellular networks October 2019", which references the FCC—which is relying on the FDA—and also references the FDA, stating:

> *"The FDA has the authority to take action if cell phones are shown to emit RF energy at levels considered hazardous to users."* This communicates that if there were a problem, the FDA would be addressing it. Further, an unsuspecting public would not be aware that in regards to the RFR exposures from cell towers and 5G "small" cell towers, there is no health and safety agency tasked to ensure safety.

The New Hampshire (NH) Commission on 5G had a minority report (page 18) penned by a group *that included New Hampshire Senator James Gray* quoting the FDA repeatedly starting with this assertion:

> *"the FDA stated that "there are no quantifiable adverse health effects in humans caused by exposures at or under the current cell phone exposure limits."*

The NH 5G Commission Minority Report, which includes *Senator James Gray*, also referenced how the FDA supported the FCC's federal RFR limits based on the FDA's review of "all" the evidence starting on page 24:

> *"The FDA stands in full support of the adequacy of the FCC's standards. The Director of the FDA's Center for Devices and Radiological Health wrote in 2018: 'Based on our ongoing evaluation of this issue and taking into account all*

available scientific evidence we have received, we have not found sufficient evidence that there are adverse health effects in humans caused by exposures at or under the current radiofrequency energy exposure limits.”"

The misrepresentation that the FDA has ensured that 5G is safe is stated by NH 5G Commission State Senator Grey in the 10/27/20 Commission Meeting on page 383:

“The FCC and the FDA have on their websites a plethora of information about the safety of 5G and 4G and 3G as they are used for the cell phone industry”.

This confusion by state agencies has gone on for years. As just one example of many letters from U.S. resident that Scarato has been sent by people trying to ensure they are protected, the Florida Department of Environmental Protection January 22, 2013 letter responding to a Florida resident raising health issues related to smart meters cites FCC limits and the FDA stating:

“In addition, the U.S. Food and Drug Administration (FDA), in collaboration with the FCC, regulates wireless technology devices such as wireless computer networks and cellular phones. FDA monitors the health effects of wireless phones and has authority to take action if wireless phones are shown to emit RF at a level that is hazardous to the user. FDA’s website is http://www.fda.gov/”

As another example, when a Washington State resident contacted the Omak school district regarding cell phones n pockets and wireless devices, the Superintendent wrote back that:

“I have no interest in addressing your concerns regarding wireless devices. Our country utilizes innumerable wireless devices in every school across the United States to educate students every day. Hundreds of students carry wireless devices in their pockets everywhere they go (including outside of school and with parent support). This is an issue that is bigger than the Omak School District and I am not willing to engage in a debate over it.”

Michael Porter

Omak School District Superintendent

~ Creating a Future for Every Child Since 1912 ~

Michael Porter <mporter@omaksd.org>

Sent: Wednesday, February 01, 2023 2:14 PM

List of state entities that inaccurately promote the FDA as assuming safety in regards to 5G small cells and/or defer to the federal government despite no safety documentation.

Florida Department of Environmental Protection	Florida Department of Environmental Protection January 22, 2013 letter *"In addition, the U.S. Food and Drug Administration (FDA), in collaboration with the FCC, regulates wireless technology devices such as wireless computer networks and cellular phones. FDA monitors the health effects of wireless phones and has authority to take action if wireless phones are shown to emit RF at a level that is hazardous to the user. FDA's website is http://www.fda.gov/"*
School District of Palm Beach County Florida	The Chief Information Officer, Information Technology Division of the School District of Palm Beach County Florida states a myth propagated by the FDA misrepresentation to the FCC in an August 17, 2021 letter that: *"National health agencies have credibly concluded that no adverse health effects have been demonstrated at radio frequency exposures that fall within established safety guidelines—and the exposures from Wi-Fi fall well below those limits."*
Virginia Department of Health	Virginia Department of Health March 12, 2020 release states, "FDA review finds no link between cell phones and cancer." "
Hawaii State Department of Health	Hawaii State Department of Health 5G Factsheet, "What You Need to Know About Radiofrequency Energy and 5G cellular networks October 2019", which references the FCC—which is relying on the FDA—and also references the FDA, stating: *"The FDA has the authority to take action if cell phones are shown to emit RF energy at levels considered hazardous to users."* This communicates that if there were a problem, the FDA would be addressing it. Further, an unsuspecting public would not be aware that in regards to the RFR exposures from cell towers and 5G "small" cell towers, there is no health and safety agency tasked to ensure safety.

Pennsylvania State Representative Mark M. Gillen	Pennsylvania State Representative Mark M. Gillen wrote a letter to a concerned constituent stating that: "The FCC also consulted federal health and safety organizations such as the Food and Drug Administration (FDA), the Environmental Protection Agency, the Occupational Safety and Health Administration, and the National Institute for Occupational Safety and Health to develop "consensus" regulations. Together, these bodies have assessed thousands of scientific studies concerning possible health effects of nonionizing radiation. All small cells installed in the United States comply with the FCC's RF guidelines. If you feel that the FCC's RF guidelines are insufficient, you may wish to contact the FCC or your U.S. Congressman and U.S. Senators, since this is within their area of jurisdiction." …Dr. Swanson testified that the technology used in small cells is more than 30,000 times below the ionizing threshold and 500 times lower than the FCC limit. His statements are supported by the FDA, the National Cancer Institute, the American Cancer Institute and the World Health Organization. Also, the Institute of Electrical and Electronics Engineers' International Committee on Electromagnetic Safety has long held that "the weight of scientific evidence supports the conclusion that there is no measurable risk associated with RF exposures" even at levels five times higher than that permitted by the FCC.
New Hampshire Senator James Gray	The New Hampshire (NH) Commission on 5G had a minority report (page 18) penned by a group *that included New Hampshire Senator James Gray* quoting the FDA repeatedly starting with this assertion: *"the FDA stated that "there are no quantifiable adverse health effects in humans caused by exposures at or under the current cell phone exposure limits."* The NH 5G Commission Minority Report, which includes *Senator James Gray*, also referenced how the FDA supported the FCC's federal RFR limits based on the FDA's review of "all" the evidence starting on page 24: *"The FDA stands in full support of the adequacy of the FCC's standards. The Director of the FDA's Center for Devices and Radiological Health wrote in 2018: 'Based on our ongoing evaluation of this issue and taking into account all available scientific evidence we have received, we have not found sufficient evidence that there are adverse health effects in humans caused by*

	exposures at or under the current radiofrequency energy exposure limits.'" The misrepresentation that the FDA has ensured that 5G is safe is stated by NH 5G Commission State Senator Grey in the 10/27/20 Commission Meeting on page 383: *"The FCC and the FDA have on their websites a plethora of information about the safety of 5G and 4G and 3G as they are used for the cell phone industry".*
Oregon Health Authority	The Oregon Health Authority 2020 Report on Wireless and Health concludes there is insufficient evidence that wireless is harmful and states that its conclusion *"is in line with conclusions on RFR exposures and health by the U.S. Food and Drug Administration…."*
Santa Clarita CA Government	Santa Clarita CA Government lists the FDA on its website SMALL CELL AND 5G HEALTH CONCERNS
Omak School District Superintendent	Michael Porter *Omak School District Superintendent email* Hundreds of students carry wireless devices in their pockets everywhere they go (including outside of school and with parent support). This is an issue that is bigger than the Omak School District and I am not willing to engage in a debate over it."

The FDA's Misrepresentations Influence at the Federal Level to Federal Policy

The FDA's influence at the federal level has resulted in a nationwide impact in terms of both federal safety limits for human exposure and for The FDA's misinformation regarding their review of the "totality" of the evidence is used by the FCC to justify maintaining their obsolete

1996 RFR exposure limits. Further, the FCC asserts that 5G is safe and has greenlighted the unrestrained deployment of massive 5G wireless instructure.

The FCC's 2019 decision that US federal safety guidelines and rules for RFR exposure- last reviewed in 1996- do not need to be updated. Despite the fact that these RFR limits are based on the assumption that heating is the only harm and do not protect against biological effects and despite the fact that the $30M National Toxicology Program (NTP) study confirmed in a highly controlled study that RFR can cause cancer and DNA damage at non heating levels challenging the basis for the FCC's 1996 limits- the FDA entirely dismissed the study and downplayed the results to the FCC, the American public and Congressional officials.

The Federal Communications Commission

The FDA misrepresentations led to FCC's 2019 decision to affirm 1996 limits.
At the federal level, the FCC used the FDA's website, public statements and the FDA's April 24, 2019 letter (that has one paragraph on RFR limits) to support the FCC's 2019 determination (after a six-year inquiry) that the FCC's 1996 human exposure limits for RFR did not need to be updated. The FCC states in its 2019 decision:

> *"After reviewing the extensive record submitted in response to that inquiry, we find no appropriate basis for and thus decline to propose amendments to our existing limits at this time. We take to heart the findings of the Food & Drug Administration (FDA), an expert agency regarding the health impacts of consumer products, that "the weight of scientific evidence has not linked cell phones with any health problems."*
>
> *"The Director of FDA's Center for Devices and Radiological Health advised the Commission, as recently as April 2019, that 'no changes to the current standards are warranted at this time.'"*
>
> *"While research on the health effects of RF energy continues, no evidence has moved our sister health and safety agencies to issue substantive policy recommendations for strengthening RF exposure regulation. Indeed, the FDA maintains that "[t]he weight of scientific evidence has not linked cell phones with any health problems"and that "the current safety limits for cell phones are acceptable for protecting the public health. Accordingly, it is imprudent to revise these scientifically accepted recommendations without appropriate evidence supporting such a change, especially when the FDA itself has found no evidence to support any revisions."*

The FDA's misinformation regarding the 50-fold 'safety margin' is used by the FCC to justify maintaining their obsolete RFR exposure limits. In 19-226, the FCC specifically references how the FDA stated there is a 50-fold safety margin in their decision not to update 1996 RFR human exposure limits and cell phone test systems:

> *"Moreover as noted by the FDA, there is no evidence to support that adverse health effects in humans are caused by exposures at, under, or even in some cases above, the current RF limits."* FCC's statement links to footnote 42, which links to the FDA's statement by Jeffrey Shuren, M.D., on the recent National Toxicology Program draft report on radiofrequency energy exposure (Feb. 2, 2018) which states, *"In fact, the current safety limits are set to include a 50-fold safety margin from observed effects of radiofrequency energy exposure."*

Members of the FCC repeatedly present FDA's misinformation, publicly stating that the FDA has reviewed the science on 5G and wireless infrastructure and determined that FCC limits are safe. As an example, FCC Commissioner Carr's December 17, 2018 letter to Senator Blumenthal and Congresswoman Eshoo presents almost all of the myths discussed in this Declaration. Despite the fact that Blumenthal and Eshoo's December 3, 2018 letter to the FCC was about the health effects of 5*G infrastructure* "small cells on towers close to libraries, close to schools, close to their homes," and the request was not about cell phone handsets, the response from the FCC communicated that the FDA had thoroughly reviewed the health effects from small cells and 5G and deemed the infrastructure safe.

The FCC spreads FDA's misrepresentations on social media as exemplified by a May 22, 2020 tweet by FCC Commissioner Carr that states "The FCC, FDA, and health + safety experts are constantly reviewing the relevant science and new studies.They've made clear that the federal RF rules are not only adequate to protect human safety, they include a wide safety margin. The federal rules apply to 5G." FCC Commissioner Carr statements are erroneous as

Brendan Carr
@BrendanCarrFCC
5. The FCC, FDA, and health + safety experts are constantly reviewing the relevant science and new studies.
They've made clear that the federal RF rules are not only adequate to protect human safety, they include a wide safety margin. The federal rules apply to 5G.
the current limits based on the currently available scientific evidence (see Letter from the FDA to the FCC on Radiofrequency Exposure - PDF 74KB).
To date, there is no consistent or credible scientific evidence of health problems caused by the exposure to radio frequency energy emitted by cell phones (see Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer – PDF 1.3MB).
The FDA's doctors, scientists and engineers continually monitor the scientific studies and public health data for evidence that radio frequency energy from cell phones could cause adverse health effects. If a credible risk is detected, the FDA will work closely with other federal partners to mitigate the risk.
7:34 PM · May 22, 2020 · Twitter for iPhone

Thus, the FDA's misrepresentation regarding the safety margin is repeated by the FCC and ultimately used to substantiate a decision to affirm RFR safety limits and cell phone radiation test protocols from 1996. In the FCC's 2019 decision, the affirmed cell phone test systems that utilize a separation distance between the phone and the body and also affirmed that the FCC does not need to do more to inform the American public about the fine print warnings.

If the FDA had been honest and transparent, the FCC might have made a different decision, but the FCC was not provided anything more than one paragraph by the FDA. The FDA could have informed the FCC about the fact that phones exceed FCC limits in body contact position and that the public does not know how to navigate the FCC database in order to learn what the FCC limits might be. Had the FDA been transparent, it would have informed the FCC that FDA had not reviewed the science on cell tower environmental RFR. However, the FDA misrepresented that it had reviewed the totality of the scientific evidence.

The FCC references the FDA's misrepresentations in its 11/9/2020 brief in Environmental Health Trust et al. v the FCC

The FCC clearly lays out how it "reasonably" relied on the FDA which reviewed the "totality" of the evidence starting on page 23:

> ***"The FCC Reasonably Relied on the FDA's Recommendation.***
> *a. The Commission properly credited the FDA's recommendation in declining to propose new exposure limits. Order ¶¶ 10-12, 15 (JA7-12). The FDA has statutory responsibility to regulate the human health effects of exposure to radiofrequency energy. Congress directed the FDA to establish an "electronic product radiation control program designed to protect the public health and safety from electronic product radiation." 21 U.S.C. § 360ii(a). In carrying out that responsibility, the FDA collects and makes available the results of research and studies regarding electronic product radiation, and the agency provides recommendations relating to its "hazards and control." 21 U.S.C. § 360ii(b)(1). The FDA also conducts ongoing evaluation of "'scientific and medical evidence related to the possibility of adverse health effects from radiofrequency energy exposure in both humans and animals.'" Order 12 n.42 (JA10) (quoting Statement from Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health on the recent National Toxicology Program draft report on radiofrequency energy exposure (Feb. 2, 2018)"*
>
> *"The FDA participated actively in the FCC's inquiry, and then released its own review of scientific literature, which confirmed the FCC's conclusions, shortly after the Order was adopted.4 In its comments before the FCC, the FDA advised that "'no changes'" to the current radiofrequency exposure limits "'are warranted at this time.'" Order 10 (JA7) (quoting Letter from Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health, FDA, to Julius Knapp, Chief, OET, FCC, ET Docket No. 13-84 at 2 (Apr. 24, 2019) (JA8187)). The "'totality of the available scientific evidence,'" the agency observed, "'continues to not support adverse health effects in humans caused by*

exposures at or under the current radiofrequency energy exposure limits.'" Id. 12 n.42 (JA10) (quoting Feb. 2, 2018 Statement from Jeffrey Shuren).

As the FDA "is the agency with primacy" in evaluating the human health effects of exposure to radiofrequency radiation, "the FCC's decision not to leap in, at a time when" the FDA "saw no compelling case for action," was manifestly reasonable."

Despite the fact that the FDA never evaluated all the potential health effects page 16 of the FCC Brief states:

"The FDA, which has specific expertise in evaluating such effects, recommended no changes to the limits."

The FCC references the FDA's opinions on its public information websites.

The FCC website on wireless devices and and health concerns states,
"The FDA further states that "the weight of the scientific evidence does not support an increase in health risks from radio frequency exposure from cell phone use at or below the radio frequency exposure limits set by the FCC" (See FDA webpage) ...The FDA maintains a website on RF issues…"

The FCC's website on RF Safety FAQ has numerous statements referencing the FDA including:

"The Commission does not regulate exposure to emissions from these devices. Protecting the public from harmful radiation emissions from these consumer products is the responsibility of the U.S. Food and Drug Administration (FDA). Inquiries should be directed to the FDA's Center for Devices and Radiological Health (CDRH), and, specifically, to the CDRH Office of Compliance at (301) 594-4654."

"The FDA, the EPA and other federal agencies responsible for public health and safety have worked together and in connection with the WHO to monitor developments and identify research needs related to RF biological effects. More information about this can be obtained at the FDA Website."

"WHAT LEVELS ARE SAFE FOR EXPOSURE TO RF ENERGY?...In the United States, the FCC has adopted and used recognized safety guidelines for evaluating RF environmental exposure since 1985. Federal health and safety agencies, such as the EPA, FDA, the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) have also been involved in monitoring and investigating issues related to RF exposure."

Local and state governments rely on the FCC which relies on the FDA:

"The village is relying on FCC guidelines, the federal agency charged with ensuring the emissions are at a level to protect the health and safety of residents and occupants of the building," he said. "We as a village rely on federal and state agencies in a variety of

different areas, whether it's car safety, drinking water levels, lead paint or (radio frequency) emissions, which are the top of cell installations."- https://www.scarsdalenews.com/top_stories/verizon-presents-plan-to-improve-cell-coverage-in-scarsdale/article_4762e728-ae49-11ed-9294-cf42472adc3e.html

The influence of FDA misrepresentations influencing the FCC goes back years.

As just one example, in an April 4, 15, 2017 letter from the FCC to Senator Nelson the FCC states that:

> *"We note that the FDA maintains on its website that it believes the weight of scientific evidence does not show an association between exposure to radiofrequency exposure and adverse health outcomes."*

FDA's Influence to Other Federal Health and Safety Agencies

Other federal health and safety agencies reference the inaccurate FDA information reiterating a false narrative of safety.

National Cancer Institute:

In June 2020, the National Cancer Institute released an article on the FDA Literature Review that was titled "FDA Says Data Doesn't Link Cell Phones to Cancer" that says:

> *"Is there any reason to worry? The best evidence says no."*

- The National Cancer Institute's Cell Phone Radiation page references the FDA rejection of the NTP and states, "*The US Food and Drug Administration (FDA) notes that studies reporting biological changes associated with radiofrequency radiation have failed to be replicated and that the majority of human epidemiologic studies have failed to show a relationship between exposure to radiofrequency radiation from cell phones and health problems."*

The National Cancer Institute communications with New Hampshire State Commission on 5G state the NCI does not review the research on RFR but instead the FCC and FDA are the responsible.

- Bill Robinson of the Office of Communications and Public Liaison of the National Cancer Institute (NCI) wrote a July 30, 2020 email to the New Hampshire 5G Commission in NCI's response to the Commission's questions that the FDA - not NCI- has the authority to issue opinions (page 31of New Hampshire Report State Report):

> **““Councilmember Denise Ricciardi - Question 3.** What is the NCI opinion on the safety of cell phones? If you have one, please share your scientific documentation.
>
> **Response from the National Cancer Institute:**
>
> The FDA and FCC are the responsible federal agencies with authority to issue opinions on the safety of these exposures. As a Federal research agency, the NCI is not involved in the regulation of radiofrequency telecommunications infrastructure and devices, nor do we make recommendations for policies related to this technology.”

The NCI stated, *“Our sister agencies, the FDA as well as the FCC, retain responsibility for reviewing guidance on safety concerns and informing the public if those circumstances change.”*

- NCI’s Robinson also wrote the NH Commission in an earlier 7/16/2020 email that the FDA had done an assessment of U.S. RFR limits- a misrepresentation by the FDA.
  > *“The FDA recently provided an updated assessment of the current limits of RF energy based on the currently available scientific evidence (see Letter from the FDA to the FCC on Radiofrequency Exposure).”* (page 38 of New Hampshire Commission Report on 5G)

The case of the middle school student and the National Cancer Institute.

A heartbreaking example of how the FDA’s misleading information leads to false safety assurances that are then amplified by government agencies which in turn impacts the public can be found in the case of the Middle school student who wrote a US government scientist requesting a campaign for safer cell phone use in light of the NTP study findings of cancer in 2016. The letter could have been a pivotal moment when the NCI and NIH considered the need for more public information on how to reduce cell phone radiation. Instead, this student was sent to the FDA website and provided information downplaying the study findings rather than encouraged.

NCI was sent a letter by a Middle Schooler asking why they are not starting a campaign for safe cell use:

> *“For my final project I am researching about the health effects of radiofrequency radiation given off by cell phones. As seen through your research the radiofrequency radiation given off by cell phones can cause cancer and or tumors in the head, neck and heart lab rats. However there are no PSAs or any commercials to inform the public about this topic which is why I am writing to you.*
>
> *Since about sixth sevenths of the entire world population has access to mobile and wireless phones, this means that these people have a possibility to get cancer from their*

cell phones. However, there is no organization that creates awareness about the possibility, no matter how small it is, of getting cancer and or tumors from one cell phone. I understand that the research for this topic is evolving, but the study you were involved in showed us that it is possible and likely than humans can get cancer and brain tumors from cell phones.

Although there are many more studies done that prove opposite to this possibility, the fact that even one study was positive shows that cancer and tumors could be created from the radio frequency given off by cell phones. I believe with the information and research found in your study, a group of well-informed people in this topic like you should create an awareness organization. Thank you for your time and I hope to hear from you."

In response the National Cancer Institute wrote:

"We hope you will understand that, as a research agency, the National Cancer Institute does not conduct public awareness campaigns. In addition, the US Food and Drug administration shares responsibility for cell phones with the FCC. Although cell phones can be sold without FDA clearance or approval the agency monitors the effects the phones have on health. FDA has the authority to take action if cell phones are shown to admit RF energy at a level that is hazardous to the user.

After sharing the two tips that the FDA has on its website about how to reduce exposure to cell phone radiation the letter reads, "you may also be interested in following enclosed NIH and NTP articles about the study" and one of the links is called ***"N I H experts cast doubt on rat study linking cell phones, tumors."*** *[we expect that article links here, further downplaying the study]*

Read the middle school student's letter here, Read the response from the National Cancer Institute here.

This exemplifies how a child understood the need to raise awareness about cell phone radiation after the NTP study but was sent to the FDA website by the NCI. Unfortunately the FDA site would provide minimal information and a few short tips on how to reduce exposure. Notably, at that time the FDA site was not updated and it had even less information than after February 20, 2020. However the outrage is that a middle schooler had to go to the government agencies that supposedly should protect the child to request action. Not only do these agencies have little information to share, but even years later, they omit life saving information, promote misleading safety assurances and have yet to protect the public as the NCI stated the FDA would do in the letter.

Note: The NCI stated they do not "conduct public awareness campaigns" but that is wrong. NCI in fact is involved in a lot of activities around awareness with its website being one vehicle for awareness. The webpage "September is Childhood Cancer Awareness Month" shares resources, the Down Home Healthy Cooking has recipes and tips for healthy cooking, Clearing

the Air has strategies to quit smoking and there is much more on the website. The NCI is not the focus of this report but they have also misrepresented the issue and this will be the subject of another forthcoming report by Scarato.

Centers for Disease Control (CDC)

The CDC webpage on cell phone radiation links readers to the FDA. Note: several of the CDC webpages were drafted with the help of an industry tied researcher.

FDA's influence to Congress

Due to the FDA's misrepresentations, U.S Congress is void of any action to address the issue of the health risks of 5G and wireless radiation because they believe there is no reason to take action. Instead of curbing 5G and wireless deployment, Congress has passed and is proposing bills that fastrack deployment of cell antennas.

Further, the Congressional committees that have oversight to the FCC and FDA have not taken any action to question these agencies on their review and risk assessment. When constituents contact their elected officials, the issue is either dismissed or fully ignored.

- Documentation of FDA's misrepresentations influencing Congress.
- Examples of how the FDA's misrepresentations result in members of Congress themselves communicating false illusions of safety to constituents.

Examples of how the FDA's misrepresentations result in members of Congress themselves communicating false illusions of safety to constituents.

As described below, letters from Senator Feinstein, Representative Anna Eshoo's, Representative Chrissy Houlahan, Senator Tammy Baldwin exemplify how the FDA's misinformation inaccurately informs our federal elected officials resulting in these esteemed legislators presenting erroneous safety assurances. The FDA misrepresentations have led to a lack of awareness regarding 1. the state of science and 2. the lack of monitoring by federal agencies.

Thinking that the FDA and federal agencies are continuously monitoring the science, many elected officials just ignore the health issues raised- as illustrated by letters from numerous officials found in this declaration under "Congress Communications to Constituents After They Raise Health Issues." Responses from Senator Markey (2017 and 2019) are void of any meaningful response to constituents who contacted him about health effects of 5G and wireless networks. The constitution who wrote Markey via his website stated they had 5 letters from him that were form letters just like the 2017 letter.

The bottom line is that 5G and wireless bills are rapidly moving through Congress receiving bi-partisan support due to this misinformation. Senator Kyrsten Sinema's letter illustrates this as she speaks of "leading the way in 5G technology." U.S. Representative Chrissy Houlahan Letter states, *"For our nation to remain on the cutting edge of innovation, we must also make strategic investments in 5G technology."*

The Congressional Committees tasked to provide oversight aren't even aware this issue is in need of oversight. Notably Senator Tammy Baldwin, Senator Feinstein and Senator Merkley are all members of the U.S. Senate Committee on Appropriations Subcommittee Agriculture, Rural Development, Food and Drug Administration, and Related Agencies that have oversight of the FDA and all have written letters void of action to ensure accountability on the issue. .

The end result is that the buck keeps getting passed to the FCC which in turn states it relies on the FDA and no one is taking responsibility.

Myth: FCC's limits are protective based on the FDA review
- US Representative Anna Eshoo Senator Jeff Merkley share FDA's misrepresentation

Timeline
On July 18, 2019, U.S. Representative Anna Eshoo and Senator Jeff Merkley wrote the FDA requesting information about the FDA's safety review of 5G and wireless.

On September 9, 2019 the FDA's Jeffrey Shuren and Edward Margerrison sent a letter in response. The FDA's letter included numerous misrepresentations including that the FDA had reviewed the totality of the evidence (even non cancer harms and 5G) and had evaluated the safety limits themselves.

Statements from the FDA letter include:

> *"FDA considers all relevant scientific data on RFR"*
> *"The Agency has taken a comprehensive approach to evaluating the scientific evidence regarding the impact of RFR exposure on human health"*
>
> *"We appreciate the opportunity to provide an overview of the substantial body of evidence that has informed our determination that the current safety standard for RFR exposure remains appropriate."*

In turn, on September 20, 2019, Representative Eshoo and Senator Jeff Merkley sent a letter to a constituent stating of the FDA:

> *"the agency concludes that the current RFR safety limits for cellphones are acceptable to protect public health. These conclusions hold for 5G technologies."*

Myth: The FCC "cooperate[s] with industry, expert agencies, and health and safety organizations to ensure that guidelines continue to be appropriate and scientifically valid."
-U.S. Senator Fienstein shares FCC's determination that is influenced by the FDA misrepresentation

A September 16, 2021 letter from U.S. Senator Fienstein repeats the myth FCC's 1996 exposure guidelines are appropriate. This unsubstantiated statement is grounded in the FDA's misinformation to the FCC that RFR limits do not need to be changed- the FDA's 2019 letter responding to the FCC's request for review of its 1996 RFR limits. Fienstein stated to a constituent that:

> *"I understand you are concerned that the deployment of 5G may expose some Americans to unhealthy levels of radio frequency. As you may know, the Federal Communications Commission (FCC) is in charge of setting the standards for radio frequency exposure to the public...Since 1996, it has been the FCC's policy to cooperate with industry, expert agencies, and health and safety organizations to ensure that guidelines continue to be appropriate and scientifically valid."*

Feinstein's letter communicates that the FCC limits are protective and science based- due to the assumed collaboration of numerous entities including US health and safety agencies. Yet the only other U.S health agency with authority to act is the FDA and this authority is only in regards to cell phones and consumer devices, *not cell tower networks.* The FDA has never clarified its policy on what level of exposure or harmful effects would trigger an action and has never publicly shown a risk assessment. Because the FDA misrepresented their level of scientific review to the FCC, the FCC refused to update their 1996 RFR limits that Senator Feinstein refers to as "scientifically valid."

Myth: Legislation that only addresses 5G security issues "would protect consumers…"
- U.S. Representative Chrissy Houlahan

When a constituent wrote to U.S. Representative Chrissy Houlahan regarding RFR health risks, the representative responded with an October 8, 2018 letter ignoring the issues raised by the constituent. Instead Houlahan shared how she cosponsored the Secure 5G and Beyond Act of 2020 which "would protect consumers…" This is just one example of elected officials nationwide that seem to be unaware that consumers need to be protected from health risks of 5G networks by a science based risk assessment.

Myth: "...We continue to study the health impacts of current and emerging technologies."
-U. S. Senator Tammy Baldwin

FDA's misinformation creates confusion and allows members of Congress to believe the illusion that US health and safety agencies of the U.S. government are studying the issue when they are not. As an example, Senator Tammy Baldwin's 2017 letter to a concerned constituent inaccurately asserts that the FDA and CDC conduct studies on cell towers.

> *"I understand your concerns about the health impacts of wireless technologies, including proximity to a cellular tower. According to studies conducted by the Centers for Disease Control and Prevention (CDC), in coordination with the Food and Drug Administration (FDA) and FCC, radio frequency emissions exposure from cellular towers is thousands of times below safety limits and significantly lower than that from emissions by television antennas and radio broadcast towers."*

Senator Baldwin then explains in the letter how she will "*closely monitor"* agencies "*to ensure that we continue to study the health impacts of current and emerging technologies."* However no US agencies are conducting research studies on cell tower radiation. The EPA was defunded from measuring RFR levels from cell towers and wireless networks decades ago. The last EPA report[144] on environmental levels of RFR was released in 1984. Baldwin's letter exemplifies the consequences of FDA's misrepresentation that agencies are actively monitoring the research or performing studies.

Baldwin then describes how on August 3, 2017, the Senate passed both the MOBILE NOW and DIGIT Acts. The DIGIT Act would create a working group to ensure that federal resources are available for home devices, such as kitchen appliances, that are Internet-enabled. The MOBILE NOW Act would facilitate the development of wireless broadband networks.

Decades of shifting responsibility to federal agencies despite no accountability at the federal level.

The implications of the FDA's decades of misrepresentation regarding its policy and scientific review has resulted in a situation where agencies at every level of government shift responsibility to the FCC limits which are being substantiated by the FDA's misrepresentations.

Local agencies assume that if there were a problem, the feds are responsible and would act. As an example after a Florida resident raised the issue of cell phone health effects, pregnancy and children's vulnerability to the Florida Department of Environmental Protection, the department responded with a January 22, 2013 letter referencing the FCC's 1996 limits and stating:

> *"In addition, the U.S. Food and Drug Administration (FDA), in collaboration with the FCC, regulates wireless technology devices such as wireless computer networks and cellular phones. FDA monitors the health effects of wireless phones and has authority to take action if wireless phones are shown to emit RF at a level that is hazardous to the user. FDA's website is http://www.fda.gov/""*

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[144] Hankin, Worbert N. "Radiofrequency Radiation Environment Environmental Exposure Levels And Rf Radiation Emitting Sources." *Document Display | NEPIS | US EPA*, 1985.

The FDA's Misrepresentation Influence to Major Legal Cases

Several federal legal cases have hinged on FDA's false safety assurances and misrepresentation that a scientific review of RFR limits exists. Due to the court decisions, the public is kept in the dark about cell phone radiation and wireless companies evade accountability.

Below are two examples where the FCC filed statements in legal cases, using the FDA's faulty statements (See FDA Shuren's February 2, 2018 statement) regarding the 50-fold safety margin and as a result the court ruled in favor of the wireless industry.

Wireless Ass'n v. City of Berkeley, 9th Cir
The FDA's erroneous information led to the September 2020 federal court ruling in favor of the wireless industry (CTIA – The Wireless Ass'n v. City of Berkeley, 9th Cir.) which effectively halted implementation of the City of Berkeley's cell phone right-to-know ordinance. This ordinance would have ensured that consumers were informed at the point of sale that: "The City of Berkeley requires that you be provided the following notice: *To assure safety, the Federal Government requires that cell phones meet radio frequency (RF) exposure guidelines. If you carry or use your phone in a pants or shirt pocket or tucked into a bra when the phone is ON and connected to a wireless network, you may exceed the federal guidelines for exposure to RF radiation. Refer to the instructions in your phone or user manual for information about how to use your phone safely*." This is a factual statement about the separation distances used for cell phone testing. As presented earlier, Scarato shared the results of the French government tests and the published research with the FDA documenting the fact that the was made aware that if consumers do not follow these distances, they could be exposed to RFR levels that exceed FCC's regulatory safety limits; the FDA is also aware that the public is unaware of the manufacturer instructions to never carry or use a cell phone directly against the body.

For several years, the City of Berkeley withstood industry lawsuits against the Ordinance based on the fact that this case was not about the controversial issue of health effects but instead was simply stating facts so that consumers would be aware of the separation distances needed to maintain the regulatory limit.

However, after the FDA's erroneous submissions to the FCC, the FCC filed a June 22, 2020 statement of interest in the Berkeley case, citing the FDA: "*the FDA's "public statements continue to support the current limits.*"

The FCC's statement cites its 2019 determination that FCC's 1996 safety limits do not need to be reviewed—because even if FCC limits were breached, the "large safety margin" was protective. The FCC's statement further alleges that cell phone RFR test methods do not need to be changed because of the alleged "large safety margin." These FCC statements all rest on the FDA's information.

Regarding the “safety margin”, the FCC states in its 6/22/2020 “Statement of Interest” court filing:

> *“the “existing exposure limits are set with a large safety margin, well below the threshold for unacceptable rises in human tissue temperature.” 2019 RF Order 14. Taking these factors into account, the FCC has found it “unnecessary” to “require [RF] testing with a ‘zero’ spacing—against the body.” “*
>
> *“The FCC has declared that RF emissions from certified cell phones “pose no health risks.” [FCC] 2019 RF Order 14. In reaching that conclusion, the Commission explained that “even if certified or otherwise authorized devices” might “produce RF exposure levels in excess of Commission limits under normal use” when used against the body, any “such exposure would still be well below levels considered to be dangerous” because the RF limits “are set with a large safety margin.”*

As a consequence, on September 17, 2020, the Court found the Berkeley Ordinance preempted by the FCC’s 2019 RF update because the FCC had determined that even if wireless devices produce RF exposure that would be in excess of FCC limits, the FDA had concluded that exposure would be well below levels considered dangerous.

The September ruling specifically cites the FDA:

> *“The FDA maintains that ‘the weight of scientific evidence has not linked cell phones with any health problems’ and that ‘the current safety limits for cell phones are acceptable for protecting the public health. As noted by the FDA, there is no evidence to support that adverse health effects in humans are caused by exposures at, under, or even in some cases above, the current RF limits. Indeed, no scientific evidence establishes a causal link between wireless device use and cancer or other illnesses.”*

Cohen et al., v. Apple, Inc

In Cohen v. Apple[145] a class of consumers sued Apple, Inc. alleging that RFR emissions from certain iPhones exceeded FCC exposure limits, presenting potential health risks that the consumers had not been warned about. An accredited testing lab recognized by the FCC tested cell phones in positions simulating a phone at 2 millimeters from the body meant to reflect a phone being carried in a pants or shirt pocket, based on actual measurements of pieces of dress shirts, T-shirts, jeans, track pants and underwear. The lab found RFR measurements exceeded FCC regulatory limits in these positions. The suit called for better disclosures related to RFR from the company because Apple misleadingly markets their phones in close proximity to the body.

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[145] “Docket for Cohen v. Apple Inc., 3:19-Cv-05322 - CourtListener.Com.” *CourtListener*, https://www.courtlistener.com/docket/16107493/cohen-v-apple-inc/. Accessed 13 Dec. 2021.

Just as they did in the Berkeley case, the FCC filed an April 13, 2020 statement of interest in the Cohen v. Apple case. This led to the Court granting Apple's motion for summary judgment, finding that the claims were preempted because they conflict with the FCC's regulatory authority over cell phones.

The FCC's April 13, 2020 statement of interest cites the FDA, stating, "the FDA's "public statements continue to support the current limits." In turn, in both the Berkeley and Cohen et al. cases the court found that claims were preempted because they conflict with the FCC's regulatory authority over cell phones, and the FCC has made a safety determination. Importantly, the FCC's filings in these cases were substantiated by the FDA's misrepresentation that the FDA adequately reviewed the science and determined FCC's RFR limits were adequate. The FCC's filing reflects the FDA's misrepresentation that there is a determined large safety factor and this means that even if RFR from cell phones surpasses FCC limits, they are still safe.

The FDA's Misrepresentation Influences the Medical Profession and Medical Authorities Resulting in the Absence of Protective Health Recommendations

Medical professionals turn to the FDA for credible information and have been misinformed by the FDA that there is *"insufficient"* evidence. In turn, these medical organizations and authorities echo the FDA misrepresentations promoting a false sense of safety. Most importantly, the end result is that respected medical authorities do not enact policy statements or health recommendations to the public or patients. Even if they do list ways to reduce RFR exposure they qualify it with statements that downplay the necessity like *"it isn't clear that doing these things will be helpful in terms of health risks"* as stated by the American Cancer Association on its website.

Evidence of FDA's misrepresentations by medical organizations.

Webmed, Medical Express and Healio Hematology/Oncology all feature stories about the FDA's finding of *"insufficient"* evidence. Exemplifying these, MD Edge Hematology and Oncology's 2020 article presents the FDA literature review and is entitled, *"FDA: Cell phones still look safe."*

Medical News Today has an article "Are bluetooth headphones safe?" with the first sentence stating, "According to the Food and Drug Administration (FDA) routine exposure to nonionizing radiation is *"generally perceived as harmless to humans."*

American Cancer Society
As an example, the American Cancer Society (ACS) cites the FDA's Literature review conclusion of "*insufficient evidence*" on its "cell phone radiation webpage" despite the fact that it is not a systematic review, not a risk assessment, nor a hazard identification study. The

American Cancer Society also perpetuates the myth that the FDA has reviewed the issue of 5G or cell tower radiation as exemplified on ACS's cell phone tower and 5G web page which has a section entitled "Do cell phone towers cause cancer?" that features the FDA 2020 Literature Review which is quoted as again concluding, "insufficient evidence to support a causal association." ACS also refers to the FDA literature review conclusions on its website page on Radiofrequency Radiation.

The FDA's misleading information on the ACS website then in turn misleads the public and government officials who consider the ACS a credible source. As an example, U.S. Representative Trone sent a letter to then EHT Director Scarato stating: "According to the NIH and the American Cancer Society, there is no strong evidence that exposure to 5G towers causes negative health effects," clearly indicating that Trone is unaware that ACS and NIH have not systematically reviewed any science on 5G cell towers.

As an example of how confused medical authorities are in regards to the FDA and cell phone radiation the Medline Medical Encyclopedia:Trusted Health Information for You inaccurately states, "*The US Food and Drug Administration (FDA) and the Federal Communications Commission (FCC) have developed guidelines that limit the amount of RF energy cell phones are allowed to give off."* However the FDA did not develop these guidelines. The FCC adopted but did not develop guidelines because it is a little known fact that in fact, no US agency developed proper safety standards for RFR as the EPA was defunded from doing so in 1996. Furthermore the FDA communicates that cell phones are safe even if the radiation levels exceed the amount they are allowed to give off.

In a news article from the Philippines Business Inquirer Philippine Radiology Oncology Society Vice-President Dr. Johanna Cañal addressed almost 400 medical professionals and oncology experts during a radiation safety symposium and citing studies from global radiation authorities like Federal Communications Commission, the American Cancer Society, and the US Food and Drug Administration (FDA), Dr. Cañal said two decades' worth of research *showed no adverse health effects linked to mobile phone use or nearby cell towers."*

The American Board of Cosmetic Surgery has a webpage Are Radiofrequency Treatments Safe? - American Board of Cosmetic Surgery that states:

> "According to the FDA, the World Health Organization has classified RF radiation as "possibly carcinogenic to humans"—right along with coffee, power lines, and body powder. However, there is no conclusive evidence that RF exposure increases cancer risk in humans, even in people regularly exposed to higher amounts of RF for their jobs. Both the American Cancer Society and Federal Communications Commission have issued extensive reports on possible impact of radiofrequency exposure."
> And
> "Radiofrequency in FDA-cleared non-surgical tissue tightening is highly controlled for your safety."

FDA's information is influencing the safety perceptions of the U.S. armed forces.

Even our military forces are told that the FDA is assuring cell phone safety. Members of our armed forces are using numerous wireless devices as part of their job and due to the FDA's information will remain unaware of any potential health effects they might be experiencing.

As an example, the U.S. Army Public Health Command has a cell phone fact sheet that references the FDA as periodically reviewing the research, stating:

> "*Who decides whether cell phones are safe? Subject matter experts from the Food and Drug Administration (FDA), the Federal Communications Commission (FCC), the Environmental Protection Agency, the National Cancer Institute, the Department of Defense, the Institute of Electrical and Electronics Engineers (IEEE) and others periodically review the research data to see if there are any potential health effects from RFR. These experts also meet and produce exposure standards and guidelines for manufacturers and users of cell phones to assure their safety. These agencies have declared publicly that cell phones conform to published standards and are safe.*"

FDA's misrepresentations impact universities and educational institutions.

The University of North Carolina at Chapel Hill Position Statement on Wi-Fi Radiofrequency Exposure repeats the illusion that FDA is actively monitoring all issues stating:

> "In addition to the Federal Communications Commission, federal health and safety agencies such as the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) have been actively involved in monitoring and investigating issues related to RF exposure."

FDA's misrepresentations influence the media

The FDA's 2020 information concluding "no harm from cell phone radiation" is referenced and linked to by numerous, heavily trafficked health websites such as MIT Technology Review, Inside Towers, ZDNET, Wall Street Journal, How Stuff Works and Bloomberg, further disseminating the message that cell phones are safe *based on the FDA's review.*

> Snopes (2022) states, "the U.S. Food and Drug Administration (FDA) also concludes that over 30 years' of scientific evidence "has not linked cell phone radio frequency with any health problems."

> Pocketables headlined, "*FDA says there's scientific evidence cell pho*nes are safe." MIT Technology Review headlined, "*No, there's no evidence that cell phones give you cancer."*

In 2018, CNN, Scientific American, Reuters, New York Times, Science, Forbes and Medscape all featured how the FDA ``disagreed" with the "clear evidence of cancer" conclusions of the National Toxicology Program. Medscape's headline exemplified the media coverage: "Cancer Fears Over Cell Phones, Again, but FDA Disagrees."

The Verge coverage read, "the FDA is still confident that the current limits on cell phone radiation are safe." The Daily Mail headline read, *"FDA insists cell phones ARE safe - despite new government study that found 'clear evidence' of link to heart and brain cancers in rats' '.*

Asbestos.com has a page on Cell Phones and Cancer which cites the FDA's 2020 Report and states *"The good news is there is currently no definitive evidence that cellphones can cause cancer.*

Wireless Companies themselves repeatedly cite the FDA. The Telecom Industry Association's FCC filing summarizes the industry message stating that *"The FDA is clear that there is no danger requiring special consideration for children."*

Cancer is not a death sentence. Myths and misconceptions about the causes of malignancies - Armenian Reporter

> "Frequent use of cell phones and smartphones is not a cause of brain cancer. This is claimed by some leading international organizations – "American Cancer Society", "National Institute of Environmental Health Sciences", "Food and Drug Administration", "Department of health and human services" based on their on the research conducted. And "Interphone" organization conducted a scientific experiment with the participation of 5,000 volunteers, collecting data on the time spent by participants on mobile phones and comparing them with the processes taking place in their body. In conclusion, there is no causal link between the use of cell phones and the development of brain cancer."

The New York Times ran an article May 2016 by Aaron Carroll entitled Why It's Not Time to Panic About Cellphones and Cancer stating:

> "Many organizations, such as the American Cancer Society, the National Institute of Environmental Health Sciences, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Federal Communications Commission and the European Commission Scientific Committee on Emerging and Newly Identified Health Risks have reviewed the collected research — there is a lot — and found insufficient evidence for a link."

Is 5G Making You Sick? Here's What Experts Say – Forbes Health states:

> “5G Fact vs. Fiction: The World Health Organization (WHO) and FDA declare 5G safe.”

The inaccurate FDA website is used to “fact check” by international press organizations. The French Agency AFP FactCheck states in “5G networks do not cause 'flu-like' symptoms | Fact Check:”

> "To date, there is no consistent or credible scientific evidence of health problems caused by the exposure to radio frequency energy emitted by cell phones," the US Food and Drug Administration says on a webpagetitled "Scientific Evidence for Cell Phone Safety."

The FDA’s Misrepresentations Allow Wireless Companies to Market Their Products As Safe

Wireless companies use the FDA’s misinformation: 1) to defend the safety of their products to the public, 2) in the courts to “win” against legal challenges from wireless safety advocates and consumer groups and 3) in their extensive lobbying campaigns designed to influence elected officials to reduce or eliminate regulation of wireless devices and infrastructure.

The wireless companies use FDA's information in defending the safety of their networks to elected officials in order to influence policy decisions.

An April 12, 2024 letter from AT&T Office of the President on 5G and Cell Towers says:

> Even so, the AT&T small cell facility near your location will follow conservative RF exposure limits adopted by the Federal Communications Commission (FCC), the federal agency responsible for regulating wireless carriers’ RF emissions. As AT&T is not an expert health agency, we must be guided by those FCC RF exposure regulations, which are based on information from expert health and safety agencies and organizations, including the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Institute for Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), the National Council on Radiation Protection and Measurements (NCRP), the American National Standards Institute (ANSI), and the Institute of Electrical and Electronics Engineers, Inc. (IEEE). The view of these health and safety organizations and other members of the mainstream scientific community is that the large body of scientific research on RF energy and health has not established a causal relationship between RF fields below the FCC RF exposure limits and adverse health effects. Here are only a few examples:
>
> - The FDA states: “The current limit on radio frequency (RF) energy set by the Federal Communications Commission remains acceptable for protecting the public health.” (https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety)

A June 7, 2019 Letter from the CTIA Wireless Industry to the Senate and House Chair of the Massachusetts Joint Committee on Public Health opposes proposed wireless bills and informs the elected officials that the FCC and other U.S. health agencies have reviewed the science and determined safety. Importantly, the CTIA repeats the FDA's misinformation stating:

> *"FCC's Commissioner Carr stated, "the FCC as well as other agencies that are experts in health and safety issues, are always looking closely at these issues, staying up to date on the latest science. They've looked at all the studies and all the information and they have reached the determination that these are safe. In addition, per the attached the consensus among health experts is that the weight of scientific evidence shows no known adverse health effects to humans from exposure to wireless antennas or devices."*

The CTIA's attached May 29, 2019 document from one of their paid consultants states:

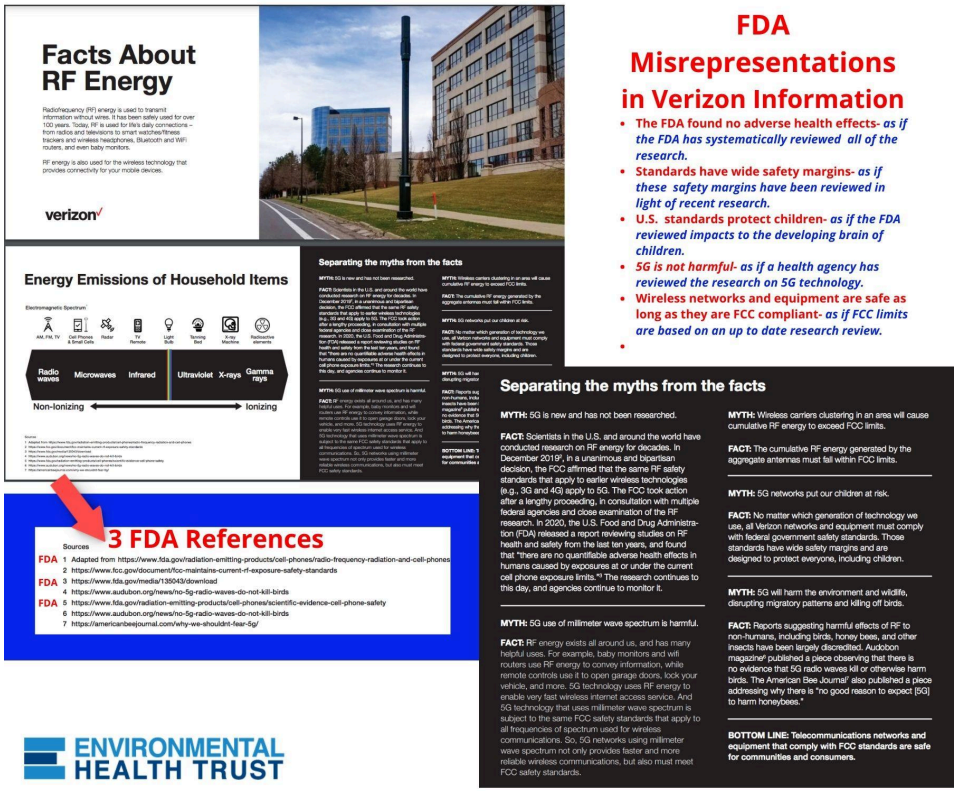
> *"Federal agencies responsible for regulating the safety of cell phones and wireless infrastructure and leading cancer and health institutions in the United States have not found any link between electromagnetic fields allowed by the FCC regulations and cancer or other adverse health effects."*
>
> Then there is a list of organizations with quotes featuring the FDA
>
> **"The Food and Drug Administration (FDA):** "*Based on our ongoing evaluation of this issue, the totality of the available scientific evidence continues to not support adverse health effects in humans caused by exposures at or under the current radiofrequency energy exposure limits." [footnote links to* ***FDA Shurens 11/2018 statement****]*

The wireless companies use this information in defending the safety of their networks to the public in order to influence public perception. The FDA has been repeatedly cited by industry andindustry's paid consultants for years, creating the illusion that the FDA supports FCC limits even though the reference itself is to the 1996 limits. The fact that the FDA has no authority in regards to cell towers is omitted and the fact that the FDA has performed zero review of the totality of the evidence is omitted.

See below a table with key examples of how the FDA's contradictory and misleading information is used by the wireless industry to promote the false narrative that cell phones, Wi-Fi devices, cell towers and 5G have been deemed safe after a robust safety review by the FDA.

Wireless Industry Document	**Documentation on How FDAs Misrepresentations are Augmented, Expanded and Amplified into Sweeping Unsubstantiated Conclusions**

CTIA Consumer Website Wireless Health Facts- Wirelesshealthfacts.com	**FDA's Misrepresentations in CTIA Statements** #1: The FDA evaluated the "totality" of scientific data. #2: The FDA's Literature Review is a scientifically valid risk assessment. #6: The NTP study is irrelevant to human health. #7: The FDA has evaluated FCC's RFR limits. #8: The FDA "continuously monitors" the science. **Statement by CTIA** *"**Are cellphones, cell towers, small cells and antennas safe?*** *[Answer] Radiofrequency energy from wireless devices and networks, including radiofrequencies used by 5G, have not been shown to cause health problems, according to the international scientific community. To cite one example, the Food and Drug Administration said, "Based on the FDA's ongoing evaluation, the available epidemiological and cancer incidence data continues to support the Agency's determination that there are no quantifiable adverse health effects in humans caused by exposures at or under the current cell phone exposure limits."* "*The Food and Drug Administration has also said that "the existing safety limits for cell phones remain acceptable for protecting the public health."* *"Cell phones don't cause cancer FDA says"* *"After reviewing the [National Toxicology Program] study, the Food and Drug Administration agreed, saying that "the existing safety limits for cell phones remain acceptable for protecting the public health."*
Verizon's Consumer Information Page	**FDA's Misrepresentations in Verizon Statements** #1: The FDA evaluated the "totality" of scientific data. #10: Children and pregnant women are protected by FCC RFR limits "*Do Wireless Phones Pose Any Special Risks to Children?: The FDA/FCC website states that 'the scientific evidence does not show a danger to users of wireless communication devices including children.'*" "In the United States, the Food and Drug Administration ("FDA") and the Federal Communications Commission ("FCC") set policies and procedures for wireless phones. The FDA and the FCC have created a joint website, "Cell Phone Facts - Consumer Information on Wireless Phones," which states that "[t]he available scientific evidence does not show that any health problems are associated with using wireless phones..."
Verizon's"Facts About RF	**FDA's Misrepresentations in Verizon Statements** #1: The FDA evaluated the "totality" of scientific data.

Energy” **brochure**	#2: The FDA’s Literature Review is a scientifically valid risk assessment. #7: The FDA has evaluated FCC’s RFR limits. #8: The FDA “continuously monitors” the science. #10: Children and pregnant women are protected by FCC RFR limits #13: The FDA has reviewed the safety of 5G and it is safe. *“BOTTOM LINE: Telecommunications networks and equipment that comply with FCC standards are safe for communities and consumers.”* 
Samsung’s Health and Safety Information	**FDA’s Misrepresentations in Samsung Statements** #1: The FDA evaluated the “totality” of scientific data. #2: The FDA’s Literature Review is a scientifically valid risk assessment. #4:The FDA found “the majority of studies” do not show harm. #5:The FDA found biological effects have not been replicated. #8: The FDA “continuously monitors” the science. #9:There is “scientific consensus” that RFR radiation is safe. #10: Children and pregnant women are protected by FCC RFR limits #11: Cell phones are safe in body contact positions.

	"*The FDA publication includes the following information: Do cell phones pose a health hazard? Many people are concerned that cell phone radiation will cause cancer or other serious health hazards. The weight of scientific evidence has not linked cell phones with any health problems.*" "Research Results to Date: Is there a connection between RF and certain health problems?- The results of most studies conducted to date say no. In addition, attempts to replicate and confirm the few studies that have shown a connection have failed." "The scientific community at large therefore believes that the weight of scientific evidence does not show an association between exposure to Radio Frequency (RF) from cell phones and adverse health outcomes." "Children and cell phones The scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers."
T -Mobile's RF Safety Webpage	**FDA's Misrepresentations in T-Mobile Statements** #1: The FDA evaluated the "totality" of scientific data. #4:The FDA found "the majority of studies" do not show harm. #8: The FDA "continuously monitors" the science. "*The FDA, based on current data, "believes that the weight of scientific evidence does not show an association between exposure to radiofrequency from cell phones and adverse health outcomes.*"
AT&T's Information on Wireless and Health Webpage	**FDA's Misrepresentations in AT &T Statements** #1: The FDA evaluated the "totality" of scientific data. #4:The FDA found "the majority of studies" do not show harm. #8: The FDA "continuously monitors" the science. "*The U.S. Food and Drug Administration (FDA) also has authority and expertise with respect to radio frequency fields and health, and has provided the FCC its expert views. The FDA concludes on its website: 'The weight of scientific evidence has not linked cell phones with any health problems.'*" "We can learn something from the approach taken by public health and regulatory officials who have experience in determining what the reports of scientific studies and reviews tell us about various health concerns. They do not look at only the latest reports.

	They evaluate and weigh all of the scientific reports together, paying particular attention to those that are of high quality and that have been confirmed by other independent scientific reports."
Crown Castle 2021 Understanding the Safety of 5G	**FDA's Misrepresentations in Crown Castle Statements** #1: The FDA evaluated the "totality" of scientific data. #4:The FDA found "the majority of studies" do not show harm. #8: The FDA "continuously monitors" the science. #13: The FDA has reviewed the safety of 5G and it is safe. "*The research is clear. The consensus of nearly seven decades of research by many of the top scientific and health communities, including the FDA, is that electromagnetic emissions at the levels allowed by FCC regulations are safe."*
GSMA Handbook on 5G, EMF Exposure and Safety The GSM Association is an industry organisation that represents the interests of mobile network operators worldwide.	**FDA's Misrepresentations in GSMA Statements** #1: The FDA evaluated the "totality" of scientific data. #4:The FDA found "the majority of studies" do not show harm. #5:The FDA found biological effects have not been replicated. #8: The FDA "continuously monitors" the science. #13: The FDA has reviewed the safety of 5G and it is safe. Under the section *'Is 5G Carcinogenic"* *"In February 2020 , the US Food and Drug Administration in a review of animal and epidemiological studies of radio signals and cancer concluded that:* *"To date there is no consistent or credible evidence of health problems caused by the exposure to radio frequency energy emitted by cell phones".'*
EMF Explained- A Website of the Australian Mobile Telecommunications Association - Webpage "US National Toxicology Program Study Results Published"	**FDA's Misrepresentations in AMTA Statements** #1: The FDA evaluated the "totality" of scientific data. #2: The FDA's Literature Review is a scientifically valid risk assessment. #4:The FDA found "the majority of studies" do not show harm. #5:The FDA found biological effects have not been replicated. #6: The NTP study is irrelevant to human health. #7: The FDA has evaluated FCC's RFR limits. *"The Food and Drug Administration (FDA) has reviewed the NTP report and issued a statement*

	We respect the recently released research conducted by our colleagues at the National Toxicology Program (NTP), which is part of the National Institute of Environmental Health Sciences within the National Institutes of Health, on radiofrequency energy exposure. When we nominated this topic for study in 1999, there were limited epidemiological and long-term animal studies investigating the effects of radiofrequency energy exposure from cellular phones. Fortunately, since then, there have been hundreds of studies from which to draw a wealth of information about these technologies which have come to play an important role in our everyday lives. *Taken together, all of this research provides a more complete picture regarding radiofrequency energy exposure that has informed the FDA's assessment of this important public health issue, and given us the confidence that the current safety limits for cell phone radiation remain acceptable for protecting the public health.* *Click here for the FDA statement"*
Verizon Improve Your Wireless North Carolina https://improveyourwireless.com/northcarolina/	**FDA's Misrepresentations in Verizon Statements** #1: The FDA evaluated the "totality" of scientific data. #2: The FDA's Literature Review is a scientifically valid risk assessment. #7: The FDA has evaluated FCC's RFR limits. #8: The FDA "continuously monitors" the science. #13: The FDA has reviewed the safety of 5G and it is safe. *"Are small cells safe?* *The Federal Communications Commission, in consultation with multiple federal agencies, sets federal government safety standards regarding small cells. Those standards have wide safety margins and are designed to protect everyone, including children, and were established after close examination of research that scientists in the US and around the world conducted for decades. The research continues to this day, and agencies continue to monitor it. Scientists have studied potential health effects of RF emissions from cell phones for decades. Based on all the research, federal agencies have concluded that equipment that complies with the safety standards poses no known health risks. And advisers to the World Health Organization have specifically concluded that the same goes for 5G equipment. In fact, the RF safety standards adopted by the United States Federal Communications Commission (FCC) are even more conservative than the levels adopted by some international standards bodies.* *FCC: The FCC provides information about the safety of RF emissions from cellular base stations on its website at: http://www.fcc.gov/oet/rfsafety/rf-faqs.html.* *FDA: The Food and Drug Administration's Cell phone website…"*

VERIZON PUBLIC HEARING ON 9/22/21 AT 6PM Glendale California: 9/22/21 testimony	**FDA's Misrepresentations in Verizon Statements** #1: The FDA evaluated the "totality" of scientific data. #12: There is a 50 times safety factor for cell phone radiation exposure limits. *"How much of harm will the increase of the RF cause? The RF exposure limits were set by the FCC in 1996, at the direction of Congress, and were reaffirmed in 2019. All FCC-regulated small cells must comply with the FCC's RF limits. As such, ExteNet's installations adhere to those standards. The public limit incorporates a fifty times safety factor, that is, the limit is set fifty times below the level where the scientific consensus shows that there may be observable effects on humans. So, with the large safety factor in place, there are anticipated no observable effects at sites that are below the FCC limits. More information can be found at the FCC RF safety page (https://www.fcc.gov/general/radio-frequency-safety-0). In addition, many household items, including microwave ovens, wireless modems, and televisions emit RF emissions and are deemed safe for everyday consumer use by the U.S. Food and Drug Administration."*
Smartlink LLC on behalf of AT and T, for City of Independence California, Staff Report May 27, 2020	**FDA's Misrepresentations in Statements** #1: The FDA evaluated the "totality" of scientific data. #7: The FDA has evaluated FCC's RFR limits. #8: The FDA "continuously monitors" the science. *"The FCC regulates RF emissions to ensure public safety. Standards have been set based on peer reviewed scientific studies and recommendations from a variety of oversight organizations, including the National Council on Radiation Protection and Measurements (NCRP), American National Standards Institute (ANSI), Institute of Electrical and Electronics Engineers (IEEE), Environmental Protection Agency (EPA), Federal Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), and National Institute for Occupational Safety and Health (NIOSH)."* ***"Although the purview of the public safety of RF emissions by the FCC was established by the Telecommunications Act of 1996, these standards remain under constant scrutiny.** All AT&T cell sites operate well below these standards, and the typical urban cell site operates hundreds or even thousands of times below the FCC's limits for safe exposure."*
Wireless Infrastructure Association Wireless	**FDA's Misrepresentations in WIA Statements** #1: The FDA evaluated the "totality" of scientific data.

Networks and Your Health: THE FACTS	#2: The FDA's Literature Review is a scientifically valid risk assessment. #8: The FDA "continuously monitors the science. #9:There is "scientific consensus" that RFR radiation is safe. #13: The FDA has reviewed the safety of 5G and it is safe. ***"The U.S. Food and Drug Administration has determined that based on all available evidence, there is "no increased health risk due to radio-frequency (RF) energy."*** *"U.S. Food and Drug Administration, Consumer Updates: No Evidence Linking Cell Phone Use to Risk of Brain Tumors, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm212273.htm"*
Verizon Wireless Letter to City of Salem Massachusetts 1/26/2021	**FDA's Misrepresentations in Verizon Statements** #1: The FDA evaluated the "totality" of scientific data. #2: The FDA's Literature Review is a scientifically valid risk assessment. #8: The FDA "continuously monitors the science. #9:There is "scientific consensus" that RFR radiation is safe. #13: The FDA has reviewed the safety of 5G and it is safe. *"You also expressed concerns about the health effects of RF emissions from Verizon's network equipment. The FCC has developed safety rules for human exposure to RF emissions in consultation with the numerous other federal agencies including the Environmental Protection Agency, the FDA and the Occupational Safety and Health Administration.… the FCC supported an adopted the standards after examining the RF research that scientists in the US and around the world conducted for decades.* ***Research continues to this day and agencies continue to monitor it. Based on that research, federal agencies have concluded that equipment that has been deployed in a manner that complies with the safety standards poses no known health risks."***
Jerrold Bushberg "Introduction to Potential Health Considerations of 5G Networks" at the Beverly Hills California Health and Safety Commission Meeting on February 24, 2020	**FDA's Misrepresentations in Bushberg Statements** #1: The FDA evaluated the "totality" of scientific data. #2: The FDA's Literature Review is a scientifically valid risk assessment. #8: The FDA "continuously monitors the science. #13: The FDA has reviewed the safety of 5G and it is safe. Video of presentation Minute 1:18:00

(See Agenda, Watch video, See full transcript)	*" It is fortunate that this [referring to the FDA] recently came out a week or so ago. It's the most recent review of all the epidemiological and animal data from the FDA and they ended with their conclusions they had these bullet points which said the FDA doctors scientists and engineers continuously monitor scientific studies and public health data for evidence that radiofrequency from cell phones could cause adverse health effects. To date there is no credible scientific evidence of health problems caused by exposure to radiofrequency energy. The gold standard for the assessment of risk to public health remains data and information that is available from studying effects on humans. The currently available epidemiological studies, public health surveillance data and supportive laboratory studies on cell phone radiation provides abundant evidence to support the FDA determination. So this is a very long report and a lot of science language in here but this was the conclusion at the end."*
Industry consultant Jerrold Bushberg's testimony March 24, 2015 to Los Angeles County	**FDA's Misrepresentations in Bushberg Statements** #1: The FDA evaluated the "totality" of scientific data. *"The facts as presented by experts, the American Cancer Society, the World Health Organization, the Food and Drug Organization among others. Each of these organizations have concluded that LA Rics Site [RFR] signals are not a health concern. The RF waves will not case DNA damage or health problems"*
Jerrold Bushberg's June 8, 2017 testimony to San Anselmo, CA on cell tower health effects	**FDA's Misrepresentations in Bushberg Statements** #8: The FDA "continuously monitors the science. *"On August 9, 1996, the Federal Communications Commission (FCC) established a RF exposure standard that is a hybrid of the current ANSI and NCRP standards...The FCC received thousands of pages of comments over a three-year review period from a variety of sources including the public, academia, federal health and safety agencies (e.g., EPA & FDA) and the telecommunications industry. The FCC gave special consideration to the recommendations by the federal health agencies because of their special responsibility for protecting the public health and safety. In fact, the maximum permissible exposure (MPE) values in the FCC standard are those recommended by EPA and FDA."* Bushberg presented nearly identical testimony over the years to numerous officials re health and safety in May 8, 2019 to Town of San Anselmo, July 18, 2015 to Oakland CA City Planning Commission,

	October 15, 2015 to Palo Alto CA, March 6, 2015 to Crown Castle on San Francisco wireless facilities, April 13, 2013 to Town of Ross, City of Laguna Beach March 14, 2007

See also Wireless Association 2016 Webpage Radio Frequency Information which references the FCC stating, “Numerous studies have been performed to assess whether mobile phones pose a potential health risk. To date, no adverse health effects have been established as being caused by exposure to radio frequency (RF) fields resulting from mobile phone use.”
The FCC webpage referenced states, “While there is no federally developed national standard for safe levels of exposure to radiofrequency (RF) energy, many federal agencies have addressed this important issue. In addition to the Federal Communications Commission, federal health and safety agencies such as the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) have been actively involved in monitoring and investigating issues related to RF exposure. For example, the FDA has issued guidelines for safe RF emission levels from microwave ovens, and it continues to monitor exposure issues related to the use of certain RF devices such as cellular telephones. NIOSH conducts investigations and health hazard assessments related to occupational RF exposure.”
CTIA Wirelesshealthfacts.com

For decades, the wireless companies have put forward the FDA’s information as proof of no harm.

The CTIA has had public information websites featuring the FDA as substantiating the safety of cell phones for several years. The FDA has never written to correct this misinformation, as far as we know.

Below is a CTIA website example from 2010
Cell Phone Health Facts 2010 Way Back Machine Version
http://www.cellphonehealthfacts.com/faq.html

> ***“What do we know about the safety of using a cell phone?***
> *Leading health organizations, such as the National Cancer Institute, the World Health Organization, the American Cancer Society, and government agencies including the Federal Communications Commission and the* ***U.S. Food and Drug Administration agree*** *that the weight of the scientific evidence has not linked the use of wireless phones with any health problems, including cancer. However, it is also generally agreed that more definitive research should be conducted in areas such as children's use and long-term use.”*

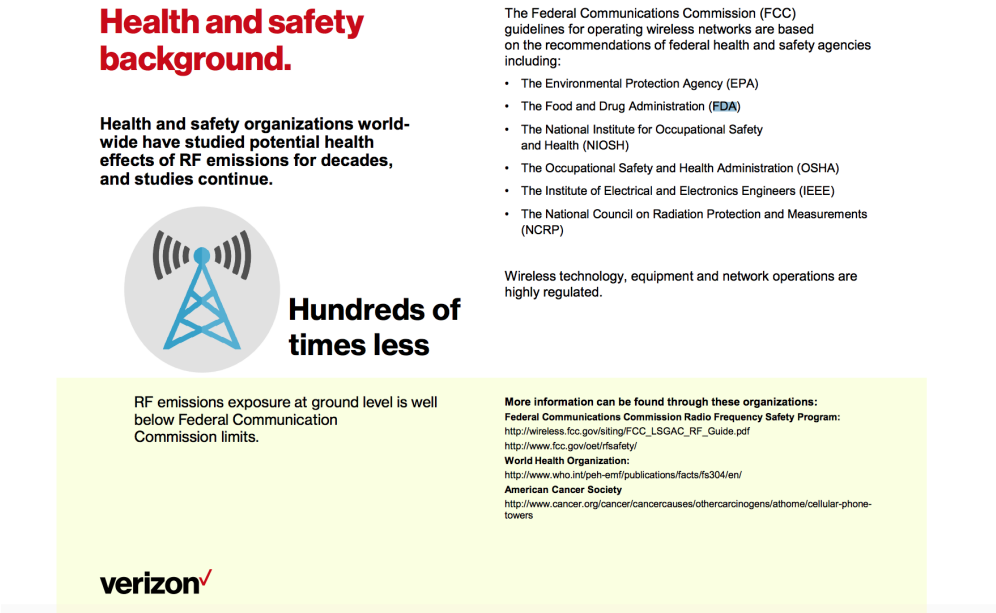
- *"[T]he weight of scientific evidence has not linked cell phones with any health problems … The majority of studies published have failed to show an association between exposure to radiofrequency from a cell phone and health problems."*
  —Food and Drug Administration
- *"The scientific community at large therefore believes that the weight of scientific evidence does not show an association between exposure to radiofrequency (RF) from cell phones and adverse health outcomes. Still the scientific community does recommend conducting additional research to address gaps in knowledge." (FDA)*
  —Food and Drug Administration

Companies have put these safety assurances (based on the FDA information) into their cell phone manuals.

T Mobile's "Consumer Information About Radio Frequency Emissions" reads:

"Are wireless phones safe? Scientific research on the subject of wireless phones and radio frequency ("RF") energy has been conducted worldwide for many years, and continues. In the United States, the Food and Drug Administration ("FDA") and the Federal Communications Commission ("FCC") set policies and procedures for wireless phones. The FDA issued a website publication on health issues related to cell phone usage where it states, "The scientific community at large … believes that the weight of scientific evidence does not show an association between exposure to radiofrequency (RF) from cell phones and adverse health outcomes."

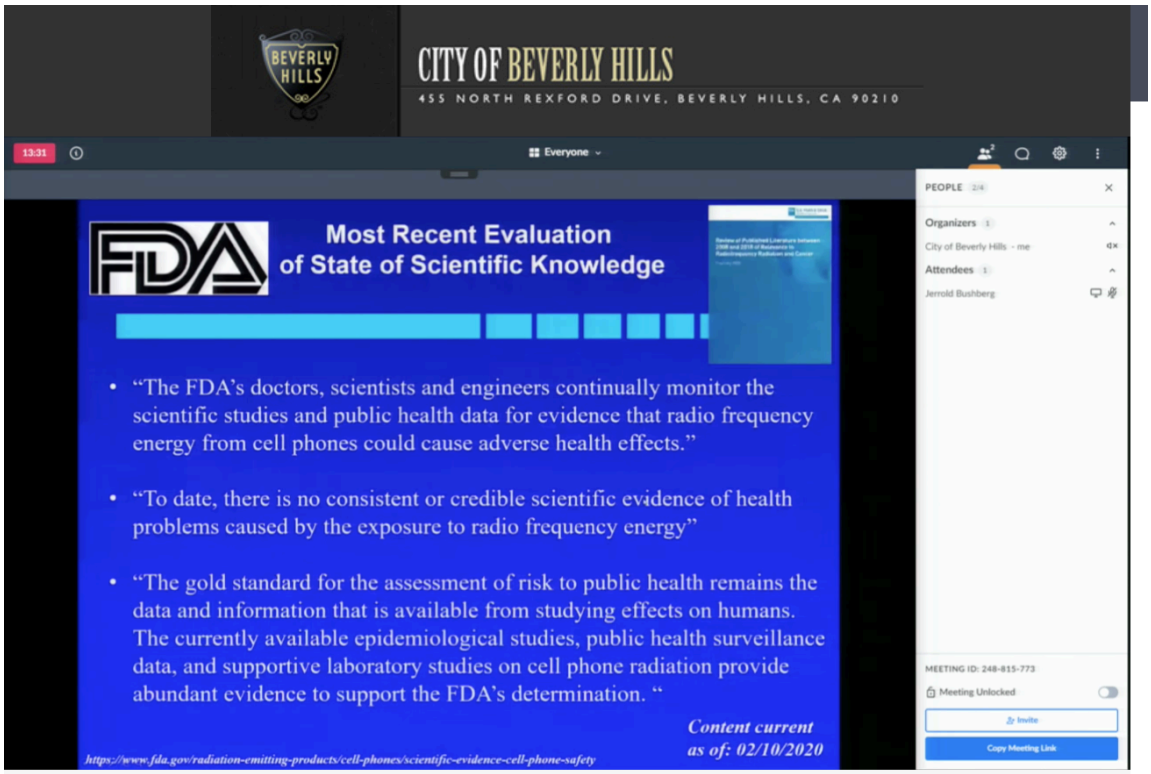
Verizon [Testimony to Coeur d'Alene Idaho, March 4, 2020]


Health and safety background.
Health and safety organizations world-wide have studied potential health effects of RF emissions for decades, and studies continue.
The Federal Communications Commission (FCC) guidelines for operating wireless networks are based on the recommendations of federal health and safety agencies including:
• The Environmental Protection Agency (EPA)
• The Food and Drug Administration (FDA)
• The National Institute for Occupational Safety and Health (NIOSH)
• The Occupational Safety and Health Administration (OSHA)
• The Institute of Electrical and Electronics Engineers (IEEE)
• The National Council on Radiation Protection and Measurements (NCRP)
Wireless technology, equipment and network operations are highly regulated.
Hundreds of times less
RF emissions exposure at ground level is well below Federal Communication Commission limits.
More information can be found through these organizations:
Federal Communications Commission Radio Frequency Safety Program:
http://wireless.fcc.gov/siting/FCC_LSGAC_RF_Guide.pdf
http://www.fcc.gov/oet/rfsafety/
World Health Organization:
http://www.who.int/peh-emf/publications/facts/fs304/en/
American Cancer Society
http://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/cellular-phone-towers
verizon

The FDA's misleading information allows scientists paid by the wireless industry to present cell towers, cell phones and wireless networks as safe.

The FDA has been repeatedly cited by industry paid scientists for years, creating the illusion that the FDA supports FCC limits even though the reference itself is to the 1996 limits. The fact that the FDA has no authority in regards to cell towers is omitted and the fact that the FDA has performed zero review of the totality of the evidence is omitted.

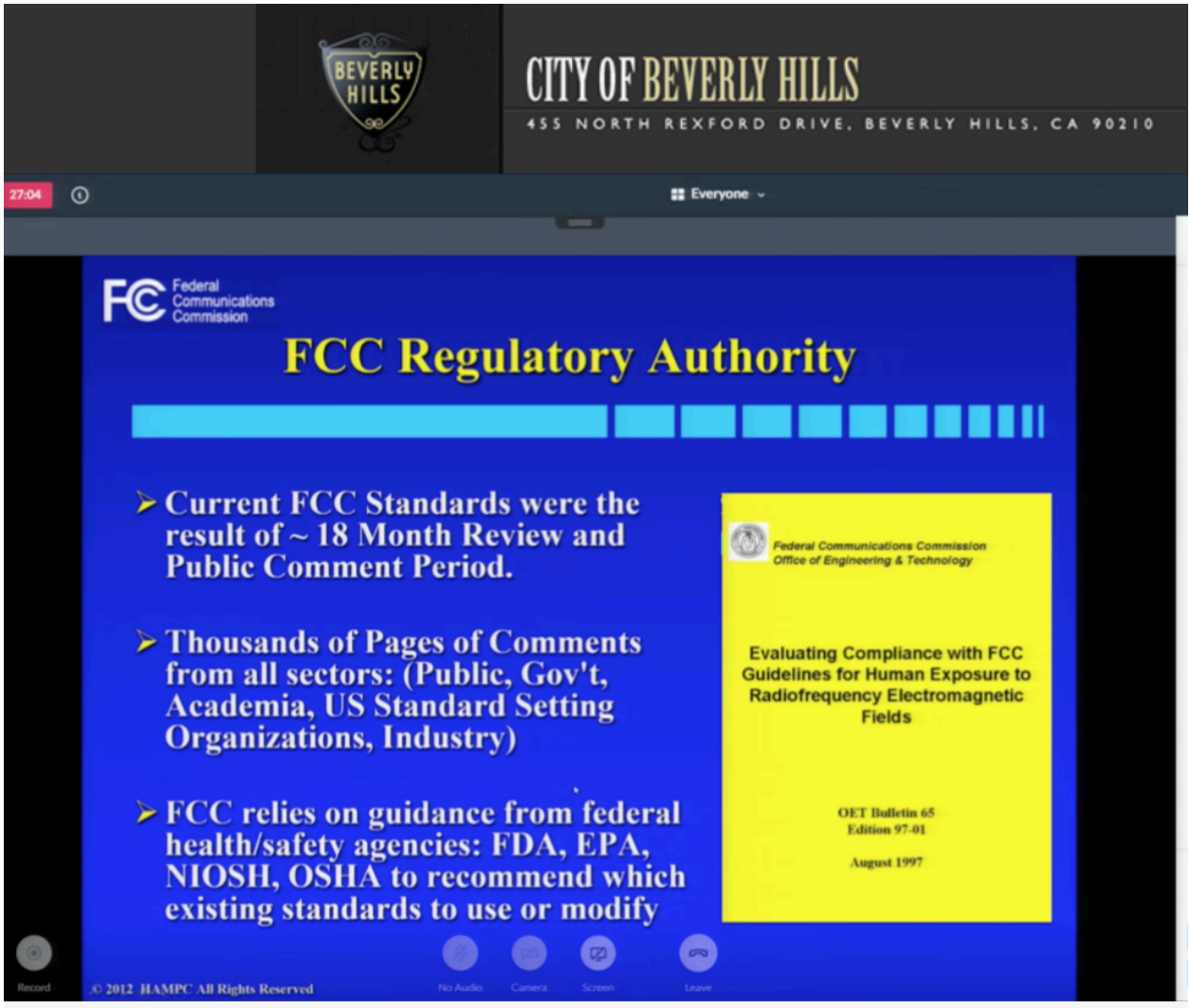
Industry consultant Jerrold Bushberg presented an "Introduction to Potential Health Considerations of 5G Networks" at the Beverly Hills California Health and Safety Commission Meeting on February 24, 2020, just days after the FDA released their literature review and updated their webpages. (See Agenda, Watch video, See full transcript) Screensaves of his presentation are below.


CITY OF BEVERLY HILLS
455 NORTH REXFORD DRIVE, BEVERLY HILLS, CA 90210
Everyone
PEOPLE
Organizers
City of Beverly Hills - me
Attendees
Jerrold Bushberg
FDA
Most Recent Evaluation of State of Scientific Knowledge
• "The FDA's doctors, scientists and engineers continually monitor the scientific studies and public health data for evidence that radio frequency energy from cell phones could cause adverse health effects."
• "To date, there is no consistent or credible scientific evidence of health problems caused by the exposure to radio frequency energy"
• "The gold standard for the assessment of risk to public health remains the data and information that is available from studying effects on humans. The currently available epidemiological studies, public health surveillance data, and supportive laboratory studies on cell phone radiation provide abundant evidence to support the FDA's determination. "
Content current as of: 02/10/2020
https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety
MEETING ID: 248-815-773
Meeting Unlocked
Invite
Copy Meeting Link
Health and Safety Commission Meeting

Bushberg featured the FDA literature review as proof of safety and as supporting the adequacy of FCC limits despite the fact that the FDA has no authority regarding cell towers and has not reviewed the full body of science on 5G, nor reviewed the RFR limits.
In his presentation Bushberg stated:

> Minute 1:18:00 *And then probably the most recently It is fortunate that this [referring to the FDA] recently came out a week or so ago.It's the most recent review of all the*

epidemiological and animal data from the FDA and they ended with their conclusions they had these bullet points which said the FDA doctors scientists and engineers continuously monitor scientific studies and public health data for evidence that radiofrequency from cell phones could cause adverse health effects. To date there is no credible scientific evidence of health problems caused by exposure to radiofrequency energy. The gold standard for the assessment of risk to public health remains data and information that is available from studying effects on humans. The currently available epidemiological studies, public health surveillance data and supportive laboratory studies on cell phone radiation provides abundant evidence to support the FDA determination. So this is a very long report and a lot of science language in here but this was the conclusion at the end." Then Bushberg goes right into discussing a cell tower site and talks about how the radiation decreases each foot away from the cell tower.


BEVERLY HILLS
CITY OF BEVERLY HILLS
455 NORTH REXFORD DRIVE, BEVERLY HILLS, CA 90210
27:04
Everyone
Federal Communications Commission
FCC Regulatory Authority
Current FCC Standards were the result of ~ 18 Month Review and Public Comment Period.
Thousands of Pages of Comments from all sectors: (Public, Gov't, Academia, US Standard Setting Organizations, Industry)
FCC relies on guidance from federal health/safety agencies: FDA, EPA, NIOSH, OSHA to recommend which existing standards to use or modify
Federal Communications Commission
Office of Engineering & Technology
Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields
OET Bulletin 65
Edition 97-01
August 1997
Record
© 2012 HAMPC All Rights Reserved
No Audio
Camera
Screen
Leave

Health and Safety Commission Meeting

This type of testimony downplaying the science showing harm has been repeatedly exemplified in his testimony over the years. Jerrold Bushberg's June 8, 2017 testimony to San Anselmo, CA on cell tower health effects which states:

> *"On August 9, 1996, the Federal Communications Commission (FCC) established a RF exposure standard that is a hybrid of the current ANSI and NCRP standards...The FCC received thousands of pages of comments over a three-year review period from a variety of sources including the public, academia, federal health and safety agencies (e.g., EPA & FDA) and the telecommunications industry. The FCC gave special consideration to the recommendations by the federal health agencies because of their special responsibility for protecting the public health and safety. In fact, the maximum permissible exposure (MPE) values in the FCC standard are those recommended by EPA and FDA."* See how Bushberg presented nearly identical testimony over the years to numerous officials re health and safety in May 8, 2019 to Town of San Anselmo, July 18, 2015 to Oakland CA City Planning Commission, October 15, 2015 to Palo Alto CA, March 6, 2015 to Crown Castle on San Francisco wireless facilities, April 13, 2013 to Town of Ross, City of Laguna Beach March 14, 2007

Industry tied groups that recommend RFR standards reiterate the misleading information of the FDA.

The August 2020 "IEEE Committee on Man and Radiation—COMAR Technical Information Statement: Health and Safety Issues Concerning Exposure of the General Public to Electromagnetic Energy from 5G Wireless Communications Networks" states under a section on "skin and ocular injury" (an issue the FDA has not shown any systematic review on) that the FDA has offered an opinion on non thermal effects:

> *"Across the whole RF spectrum, questions about possible nonthermal (not heat related) hazards have long been discussed, but neither IEEE, ICNIRP, nor health agencies have considered the evidence for these persuasive at exposure levels below current limits (ICNIRP 2009; HC 2015; IEEE 2019; SSM 2019; US FDA 2020)."*

The IEEE publication[146] also referenced the FCC limits as substantiated by the FDA:

> *"In the US, RF exposures are regulated by the Federal Communications Commission (FCC). IEEE and ICNIRP limits were last updated in 2019 and 2020, respectively. The current version of the FCC limit was approved in 1996 (FCC 1997), but in August of 2019, the FCC issued a press release stating that it intends to maintain its current RF exposure safety standards, citing a statement from the Director of the US Food and Drug Administration Center for Devices and Radiological Health that "the available scientific evidence to date does not support adverse health effects in humans due to exposures at or under the current limits.""*

[146] Bushberg, J. T., et al. "IEEE Committee on Man and Radiation—COMAR Technical Information Statement: Health and Safety Issues Concerning Exposure of the General Public to Electromagnetic Energy from 5G Wireless Communications Networks." *Health Physics*, vol. 119, no. 2, Aug. 2020, pp. 236–46. *PubMed Central*, https://doi.org/10.1097/HP.0000000000001301.

> *"The scientific basis of the limits is supported by reviews of the scientific literature by expert panels convened by health agencies or other official entities...The US Food and Drug Administration (FDA) published an in-depth review of epidemiology and laboratory studies on RF relevant to cancer published between 2008 and 2018 with selected updates through August 2019; the frequencies used in these studies were almost all between ~800-2,500 MHz, which cover 2-4G cellular frequencies. The FDA concluded (US FDA 2020): "Based on the studies that are described in detail in this report, there is insufficient evidence to support a causal association between RFR exposure and tumorigenesis. There is a lack of clear dose response relationship, a lack of consistent findings or specificity, and a lack of biological mechanistic plausibility."*

The FDA's influence to the public

- The public believes cell phones, 5G and wireless are safe.
- The public is not provided consumer information about the fact that cell phones could violate FCC limits at body contact. Courts are ruling that to do so would be "overwarning" due to FDA's influence to the FCC.
- The public is at risk of brain cancer and numerous other irreversible health impacts.

The public falsely believes cell phones, 5G and wireless are safe.

The public is left in the dark and unknowingly is putting themselves at risk. FDA's misleading information results in a perception by the media, elected officials, medical organizations and government agencies that, "No, there's no evidence that cell phones give you cancer" as headlined by MIT's Technology review in its article on the FDA 2020 Report. The public reads the FDA webpages and media reports and most will believe that cell phone radiation has been given a clean bill of health.

As exemplified in ZDNET's article reads:

> *"Do cell phones give you cancer? There's no evidence for it, says US's FDA: FDA reviews 11 years of scientific studies on cell phone use and concludes there is no harm to humans."*

The public is not provided consumer information about the fact that cell phones could violate FCC limits at body contact after court rulings that to do so would be "overwarning." This is due to FDA's influence to the FCC.

The FDA's misrepresentations lead to the public being withheld information about cell phone fine print warnings due to court rulings impacted by the FDA. Further the public who does become aware is not able to get redress in court.

Despite the fact that cell phones and other wireless devices violate FCC's human exposure limits when transmitting close to the body, the FDA has declared- as discussed earlier- *without sharing a systematic and robust scientific review* that "a 50-fold safety margin" exists and thus creating the illusion that even if limits are exceeded, *the public will not be harmed.* In turn, the FCC chose not to change the FCC's 1996 rules related to the positions that cell phones are radiation tested in. In turn, the FCC filed statements in major lawsuits asserting that phones are safe even if the RFR energy absorption exceeds FCC limits. As a consequence, the industry was successful in halting the Berkeley Cell Phone Right to Know Ordinance that would have informed people about the manufacturers' fine print warnings. And as a consequence, the wireless companies are shielded from accountability as in the case of Cohen et al v. Cohen and the public is not warned.

Thus, despite the fact that regulatory limits are violated when people hold cell phones to their skin, companies are allowed to market their devices as safe to carry and use on and against the skin. Despite the research indicating numerous risks from chronic exposure, governments are supporting wireless systems in schools and allowing cell towers 30 from homes on neighborhood streets. If people allege risk or damages, companies are able to avoid liability pointing to FCC guidelines and decisions which are based on FDA's misrepresentations.

A Remedy Is Needed As the FDA's Failure to Act Will Lead To Continued Harm

The remedy needed for the FDA is honesty and transparency.

A short list of actions: The FDA must factually present their level of review regarding radiofrequency. The FDA should clarify to members of Congress and other agencies the limits of its activities. The FDA should offer corrections when the media or Congress or other federal agencies misrepresent their activities. The FDA should be testing cell phones and other wireless devices for radiation levels in positions close to the body and publicly posting the results. Devices that exceed RF limits should be taken off the market. The FDA must clarify the process by which they "monitor" the research and release all reports and memos and agendas related to their activity on the issue. They must allow public comment

to their decisions and be transparent in every action they take. They must stop misrepresenting the NTP study findings and do a proper quantitative risk analysis on the NTP data and body of research to determine human health risks. They must have a robust webpage on how to reduce exposure that includes reducing exposure to the myriad of wireless devices in our lives today- not four tips on cell phones. Most importantly the FDA should state “we recommend people reduce cell phone and wireless radiation.”

American Families, Children and Future Generations are at Risk.
If the FDA continues to misrepresent their level of review which in turn allows this issue to remain unattended and under regulated, the public will continue to be at risk not only for increased cancers but for numerous other irreversible health impacts related to exposure. Wireless is ubiquitous and children are exposed from before they are born. Children, pregnant women and the medically vulnerable will be most impacted.

Federal Inertia: A Continued Lack of Federal Accountability and Inadequate Oversight.

Cell phone, wireless and cell tower radiation is a public health issue that requires robust evaluation by U.S. federal agencies that protect public health and the environment. However the FDA's lack of a clear policy paired with its misrepresentations regarding the FDA’s level of review has resulted in the complete failure of the United States to adequately regulate the exposure and ensure the public and environment are protected.

Elected officials at every level of government point to the FCC regulations and the FDA online statements as proof of safety. Most inaccurately believe the FDA and FCC are properly reviewing the research and are unaware that the EPA was defunded from developing safety limits. Local and state officials say their “hands are tied” and it is a federal issue. Yet at the federal level the ball has been dropped because federal officials assume the health agencies are doing their job. There has been no robust research review to evaluate the adequacy of FCC limits and no risk analysis to ensure the public is protected from long term exposures. Thus the health issue is effectively unregulated with no oversight. Although the recent EHT et al v. FCC DC Circuit court ruling brought attention to the FCC’s improper reliance on the limited information from the FDA, the FCC has no deadline on when the FCC must respond to the Court and the process could take years.

The Economic Impact

The national costs from FDA’s inaction to protect the public must be considered. Studies indicate that those who begin using either cordless or mobile phones regularly before age 20 have greater than a fourfold increased risk of ipsilateral glioma. Given that treatment for a single case of brain cancer can cost between $100,000 for radiation therapy alone and up to $1 million depending on drug costs, the financial implications could be staggering, even with a small increase in the population. Resources to address this illness are already in short supply and not universally available in all communities.

However, brain cancer is just one of the numerous health effects research has associated with RFR. Research has repeatedly found oxidative stress from exposure, which over time can contribute to a myriad of health effects. Oxidative stress plays an important role in DNA damage process, general and specific gene expression and cell apoptosis. The brain has a high metabolic rate, making it more prone to damage by ROS and oxidative damage compared to other organs. Research has also found memory damage, behavior problems and neurological damage from radiofrequency radiation exposure which could result in cognitive and behavioral impairment that can affect children's lifelong success. The economic costs could be staggering. Consider the economic impacts of other toxic exposures. Smoking-related illness in the United States costs more than $300 billion each year. The estimated U. S. annual healthcare costs from asbestos-related mesothelioma alone is nearly $2 billion, while remediation efforts cost an estimated $3 billion. Health care costs and compounded by loss of productivity and litigation costs. We expect the issue of cell phones, wireless and 5G to follow the path of lead, asbestos and cigarettes. The health and economic costs will be unprecedented.

The bottom line is that FDA's websites and letters promote the unsubstantiated narrative that wireless radiation is safe and that FCC limits are protective because the *FDA has a scientific review process in place whereby FDA scientists have thoroughly reviewed all of the latest science and used science based best practice methods to ensure FCC's RFR safety limits are safe for the public, even children.*

Despite the FDA's knowledge of research indicating harmful effects, the FDA has concealed its activities and misled the public, members of Congress and other federal agencies about its role and activities. These false safety assurances influence the public, government officials and medical professionals. As a result, consumers continue to use phones and wireless devices in ways that increase their RFR exposure and officials do not promote policy that reduces exposure but instead support policy that increases exposures. 5G streamlining bills have been passed in half the country, fast tracking the proliferation of thousands of new short cell towers to connect new 5G cell phones and other wireless devices.

X. Appendix of Evidence of FDA Misrepresentations, and Influence to Congress, State Agencies and the Media

This section lists the evidence used in this Declaration including FDA Letters and communications as well as letters by other agencies and officials related to the FDA's misrepresentations.

FDA's Public Statements, Letters and Communications

FDA's Public Website Over the Years

Theodora Scarato has monitored the FDA website for years. On February 10, 2020, the FDA updated all its website pages related to cell phone radiation after ten years of no changes. Previous to that the FDA had a long list of Q and As that did underscore the need for more research.

1. The FDA website pages after February 10, 2020 proclaiming cell phone safety and featuring the Literature Review.
    - Do Cell Phones Pose a Health Hazard?[147]
    - Children and Teens and Cell Phones[148]
    - Scientific Evidence for Cell Phone Safety[149]
    - Radio Frequency Radiation and Cell Phones[150]
    - Reducing Radio Frequency Exposure from Cell Phone Radiation[151]
2. FDA Webpages 2009 to 2019 (Previous to February 10, 2020 Saved on Wayback Machine)
    - Do Cell Phones Pose a Health hazard?[152]
    - Children and Cell Phones[153]
    - Current Research Results[154]
    - Radiofrequency Background[155]

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[147] "Do Cell Phones Pose a Health Hazard?" (2020) https://www.fda.gov/radiation-emitting-products/cell-phones/do-cell-phones-pose-health-hazard.

[148] "Children and Teens and Cell Phones." U.S. Food and Drug Administration (2020) https://www.fda.gov/radiation-emitting-products/cell-phones/children-and-teens-and-cell-phones

[149]"Scientific Evidence for Cell Phone Safety." U .S. Food and Drug Administration. (2020) https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety.

[150] "Radio Frequency Radiation and Cell Phones." U.S. Food and Drug Administration. (2020) https://www.fda.gov/radiation-emitting-products/cell-phones/radio-frequency-radiation-and-cell-phones.

[151] "Reducing Radio Frequency Exposure from Cell Phones." U.S. Food and Drug Administration. (2020) https://www.fda.gov/radiation-emitting-products/cell-phones/reducing-radio-frequency-exposure-cell-phones

[152] Electromagnetic Biology and medicine, https://www.tandfonline.com/doi/figure/10.1080/15368378.2016.1220389: 07 Feb. 2019; archived at Wayback Machine, https://web.archive.org/web/20190207225334/https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/CellPhones/ucm116282.htm.

[153] Center for Devices and Radiological Health. "Children and Teens and Cell Phones." U.S. Food and Drug Administration. FDA: 16 Dec 2019; archived at Wayback Machine, https://web.archive.org/web/20191216191346/https://www.fda.gov/radiation-emitting-products/cell-phones/children-and-cell-phones.

[154]Current Research Results. U.S. Food and Drug Administration. FDA 16 Dec 2019; archived at Wayback Machine, https://web.archive.org/web/20191216191422/

[155] Center for Devices and Radiological Health. "Radio Frequency Radiation and Cell Phones." U.S. Food and Drug Administration. https://www.fda.gov/radiation-emitting-products/cell-phones/radio-frequency-radiation-and-cell-phones: 16 Dec 2019: archived at Wayback Machine, https://web.archive.org/web/20191216191507/https://www.fda.gov/radiation-emitting-products/cell-phones/radiofrequency-background.

    - Reducing Exposure: Hands-free Kits and Other Accessories[156]
3. Pre 2009 FDA website pages- a few examples saved on waybackmachine.
    - 2004 Cell Phones Questions & Answers
    - Cell Phones and Cancer: No Clear Connection March 9, 2001, February 28, 2002

Official FDA Statements and Reports Posted Online

1. The FDA Literature Review "Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer, February 2020
2. FDA Jeffrey Shuren Submission to the FCC Docket 13-84 stating that scientific evidence to date does not support adverse health effects, April 24, 2019
3. FDA Press Release, Statement from Jeffrey Shuren, M.D., J.D., Director of the FDA's Center for Devices and Radiological Health on the National Toxicology Program's report on radiofrequency energy exposure, November 1, 2018
4. FDA Press Release, Statement from Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health on the recent National Toxicology Program draft report on radiofrequency energy exposure, February 2, 2018

FDA Letters and Email Communication Chains

FDA to Scientists

1. One sentence letter by FDA's Dr. Shuren to Theodora Scarato March 24, 2020

February 27, 2020 Letters Sent to the FDA by Scientists Calling For a Retraction of the Literature Review. Main EHT page detailing the Scientists's Letters to the FDA

- Letter calling for a retraction signed by numerous scientists.
- Ronald Melnick PhD's letter to the FDA on the National Toxicology Program study
- Albert Manville PhD, retired Senior Wildlife Biologist, Division of Migratory Bird Management, U.S. Fish & Wildlife Service, Senior Lecturer, Johns Hopkins University
- Prof. Tom Butler of the University College in Cork, Ireland's letter to the FDA
- Igor Belyaev, PhD, Dr. Sc. Head, Department of Radiobiology of the Cancer Research Institute, Biomedical Research Center of the Slovak Academy of Science
- Paul Heroux PhD, McGill University
- Alfonso Balmori, BSc
- PDF of all letters and statements

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[156] Center for Devices and Radiological Health. "Reducing Radio Frequency Exposure from Cell Phones." U.S. Food and Drug Administration. FDA. https://www.fda.gov/radiation-emitting-products/cell-phones/reducing-radio-frequency-exposure-cell-phones: 16 Dec 2019: archived at Wayback Machine, https://web.archive.org/web/20191216191229/https://www.fda.gov/radiation-emitting-products/cell-phones/reducing-exposure-hands-free-kits-and-other-accessories.

2. FDA Letter to Physicians for Safe Technology Dr. Cindy Russell and Dr. Beatrice Golomb stating that the NTP study supports the FDA determination that current safety limits for RFR are adequate and also in regards to electromagnetic sensitivity, the FDA does not believe electromagnetic fields are the cause of symptoms, May 23, 2019
3. FDA Letter to Dr. Ron Melnick in response to Dr. Melnick and other scientists asking for corrections regarding the NTP final reports. March 14, 2019

Theodora Scarato to FDA's David Kassiday:
Years of Email Communications Between Theodora Scarato and FDA's David Kassiday before and after after September 23, 2014 meeting between Theodora Scarato and Devra Davis and FDA staff

1. September 15, 2014 on FDA's activities (general statements about FDA monitoring research, interagency workgroup. When asked "What information you already have reviewed?" the answer was "FDA has reviewed many papers, presentations, and reports." The FDA states they reviewed the CERENAT study but it was never posted anywhere online
2. Scarato to Kassiday on Wi-Fi devices at body contact November 1, 2014
3. 2/5/2016 email chain FDA did not do a formal review in 2013 and no answer to question about review of FCC limits as protective
4. Email from FDA's David Kassiday to Scarato, October 18, 2017,
5. A series of email communications (2014 to 2016 Emails, 2017 Emails) over several years between FDA's Daniel Kassiday and Theodora Scarato after an in-person meeting at the FDA between Dr. Devra Davis and Theodora Scarato and FDA's Daniel Kassiday and Michael D. O'Hara.
6. FDA Communications Between Theodora Scarato and FDA Branch Chief, Postmarket and Consumer Branch Division of Industry and Consumer Education Tonya Wilbon on February 19, 2020 and FDA Consumer Safety Officer, Division of Industry and Consumer Education Counsel Terri Garvin on February 12, 2020.

Letters To and From Members of Congress

2019 FDA/Scientists/U.S. Representative Anna Eshoo and Senator Jeff Merkley

1. FDA Jeffrey Shuren and Edward Margerrison Letter to Representative Anna Eshoo and Senator Jeff Merkley summarizing how they determined FCC limits were adequate and 5G health effects were not a concern, September 9, 2019

Scientists Respond to the FDA's September 9, 2019 Letter to Representative Eshoo

- Dr. Devra Davis/ Environmental Health Trust to Eshoo Letter: October 19, 2019 Scientific letter with extensive citations documenting the published scientific evidence with counters statements by the FDA that RF is safe/brain tumors are rising in youth in the USA, Cancer is not only health endpoint showing effects, calls for Congressional hearing.

- Bioinitiative Letter to FDA Shuren, September 26, 2019 urging the FDA to rescind the endorsement of the adequacy of RF limits/ no independent review of research/ grossly outdated and incomplete information on FDA website.
- California Brain Tumor Association Letter September 30, 2019

- Physicians For Safe Technology Letter to Eshoo October 1, 2019 documenting a "number of inconsistencies, misstatements and flaws in the research summaries" put forward by the FDA. FCC to Congress Communications That Reference to the FDA
- FCC Commissioner Carr Tweet About FDA May 22, 2020

U.S. Senator Richard Blumenthal and U.S. Representative Anna G. Eshoo

- U.S. Senator Richard Blumenthal and U.S. Representative Anna G. Eshoo Letter to FCC Commissioner Brendan Car About 5G Health Hazards, December 9, 2018
- FCC Commissioner Carr letter to U.S. Senator Richard Blumenthal and U.S. Representative Anna G. Eshoo, December 17, 2018

U. S. Representative Andy Kim

- U.S. Representative Andy Kim Letter to FCC Chair Ajit Pail About Health Effects of 5G March 28, 2019
- FCC Letter Responding to Representative Kim, April 30, 2019

U.S. Representative Thomas Suozzi

- U.S. Representative Thomas Suozzi Letter to FCC, April 16, 2019
- FCC Letter Responding to Representative Suozzi, April 30, 2019

U. S. Representative Peter A. DeFazio

- Representative Peter A. DeFazio Letter to the FCC and FDA, April 15, 2019
- FCC Letter Responding to Representative DeFazio, April 30, 2019

U.S Senator Van Hollen 2024

- FCC to U.S. Senator Van Hollen

Citizens Petition

- FDA Denial of Petition Docket FDA 2013-P-1374 to Frederick S. Mayer, July 17, 2017
- Petition by Frederick S. Mayer to the FDA
- Supplemental Material in Mayer Petition to the FDA

FCC Julius Knapp Letters to Questions Re: Smartmeters and Health

- FCC Chair Letter to U. S. Senator Tim Scott Smartmeters, May 5, 2017
- FCC Julius Knapp Letter to Senator Nelson April 4, 15, 2017
- FCC Chair Julius Knapp letter to U.S. Representative Lynn Woolsey on Smart Meters, April 21, 2011
- FCC Chair Knapp Letter to Cindy Sage, August 6, 2010

National Cancer Institute Communications

- Middle School Student to the National Cancer Institute, June 18, 2016
- National Cancer Institute to Middle School Student, December 14, 2016

Congress and FDA Communications

U.S. Representative Anna Eshoo and Senator Jeff Merkley's

- U.S. Representative Anna Eshoo and Senator Jeff Merkley's letter to the FDA on 5G July 18, 2019
- FDA Jeffrey Shuren Response to U. S. Representative Eshoo, September 9, 2019
- U.S. Representative Eshoo Letter to Constituent, September 20, 2019

2020 Letters between FDA and Senator Tammy Baldwin Refuse to Answer Direct Questions

- FDA Letter to U.S. Senator Tammy Baldwin states the FDA performed an "extensive risk analysis" and determined insufficient evidence to demonstrate a causal link between cell phones and cancer…" September 8, 2020

Congress Communications of Safety to Constituents After They Raise Health Issues

- U.S. Senator Bernie Sanders January 31, 2024
- U.S. Senator Peter Welch January 3, 2024
- U.S. Senator John Hickenlooper, January 3, 2024
- U.S. Senator Alex Padilla October 23, 2023
- U.S. Senator Angus King, October 17, 2023
- U.S Representative Rashida Tlaib August 30, 2023
- U.S. Senator Schumer July 22, 2022
- U.S Senator Schumer July 21, 2023
- U.S. Senator Schumer May 11, 2023 Letter on electromagnetic sensitivity
- U.S. Senator Angus King, March 31, 2023
- U.S. Senator Tammy Duckworth January 26, 2023
- U.S Senator Schumer, February 6, 2023
- U.S. Senator Sherrod Brown Letter to Constituent April 23, 2022
- U.S. Senator Diane Feinstein Letter to Constituent February 25, 2022
- U S. Representative Scott Fitzgerald to Resident November 5, 2021
- U.S. Representative Alan Lowenthal to a Constituent on 5G, October 18, 2021
- U.S. Senator Kyrsten Sinema Letter to Constituent October 7, 2021
- U.S. Representative Trone letter to Scarato on 5G October 27, 2021
- U.S. Representative Chrissy Houlahan letter to Constituent, October 8, 2021
- U.S. Representative Trone Letter on 5G Towers September 20, 2021
- U.S. Representative Brad Wenstrup Letter to Constituent, September 16, 2021
- U.S. Senator Diane Feinstein Letter to Constituent, September 6, 2021
- U.S. Senator Schumer June 4, 2020
- U.S. Senator Sherrod Brown Letter to Constituent, September, 26, 2019
- U.S. Representative Anna Eshoo, September 20, 2019

- U.S. Representative Brad Wenstrup September 17, 2019
- U.S Senator Tammy Baldwin Letter on 5G to Constituent, November 4, 2019
- U.S. Representative Chrissy Houlahan Letter to Constituent October 8, 2018
- U.S. Senator Markey Letter to Constituent Ignores 5G Issue September 18, 2018
- U.S. Senator Tammy Baldwin Letter to Constituent September 13, 2017
- U.S. Senator Markey Letter to Constituent After Health Issues Raised July 26, 2017

State

New Hampshire Commission

- FDA's Karen Meister Letter to Denise Ricciardi of the New Hampshire Commission on 5G found on the Commission's Final 5G Report page 41. Emails dated June 23, 2020, July 15, 2020, July 15, 2020, March 2, 2020

State Entities and Officials

- Maryland Governor Hogan to Theodra Scarato November 24, 2021
- Connecticut State Senator Kevin Witkos Letter to Constituent, September 7, 2021
- New York State Senator James F. Gaughran Letter to the FCC, July 23, 2019
- Maryland Department of Public Health Letter, April 23, 2014
- Florida Department of Environmental Protection to Florida Resident, January 22, 2013
- Florida Department of Environmental Protection Letter, January 22, 2013
- State Senator Fitzgerald Office tells Constituent it is a Federal Issue, December 13, 2011
- Wisconsin Department of Natural Resources, December 12, 2014
- Pennsylvania State Representative Mark M. Gillen wrote a letter to a concerned constituent , October 4 2019

Local Officials, Government Agencies and Entities

- County Commissioner Palm Beach County Florida, September 20, 2021
- Montgomery County MD Councilman Hans Riemer newsletter July 28, 2021
- Montgomery County MD Councilman Hans Riemer Tweet July 14, 2021
- Colin Groff Assistant City Manager Boynton Beach Letter to Resident, November, 3, 2020 and November 2, 2020
- Robert Bessel Selectman Town of Canton, Connecticut Letter, March 18, 2020
- Questions and Responses from Verizon Representatives Hempfields School District Board Meeting, November 14, 2017
- Chad Pelishek Director of Planning & Development City of Sheboygan October 21 2021
- University of Maryland Letter citing FCC and ICNIRP limits, January 15, 2015
- Montgomery County School District Letter on FCC and FDA Safety Assurances, March 12, 2014
- Town of Tucson Arizona -FAQs on Small Cells References FDA
- Glendale California: 9/22/21Verizon testimony
- **City of Sacramento 5G FAQS: WHO DETERMINES SAFETY STANDARDS FOR 5G?**

The Public Service Commission of Wisconsin, Smartmeters and several U.S. residents: An example of how the FDAs lack of clear policy impacts the American people

- Public Service Commission of Wisconsin Letter to Resident, May 28, 2003
- Public Service Commission of Wisconsin to resident April 27, 2010
- Public Service Commission of Wisconsin Letter to Resident, February 10, 2011
- Public Service Commission of Wisconsin Investigation into the Health and Safety and Other Aspects of Advanced 5-WI-101 Meter Infrastructure Systems for Water Utilities, September 12, 2012
- Wisconsin Public Service Commission Denies Rehearing November 8, 2013

Wireless Industry Safety Assurances That Refer to the FDA

Wireless Company Online Websites

- CTIA Consumer Website Wireless Health Facts- Wirelesshealthfacts.com
- Verizon's"Facts About RF Energy" brochure
- Verizon's Consumer Information Webpage
- Samsung's Health and Safety Information
- T Mobile's RF Safety Webpage
- AT&T's Information on Wireless and Health Webpage
- Crown Castle Understanding the Safety of 5G
- Wireless Infrastructure Association Wireless Networks and Your Health: THE FACTS
- Times of San Diego features CTIA Protecting Health and Safety
- GSMA Handbook on 5G, EMF Exposure and Safety
- EMF Explained- Australian Mobile Telecommunications Association - website: US National Toxicology Program Study Results Published - features Statement by FDA Shuren

Wireless Industry Testimony and Communications

- AT &T Office of the President Letter April 12, 2021
- Eric Swanson Testimony to Virgin Islands Mar 24, 2021
- Christopher Davis Testimony to Farragut Planning Commission (minute 21.58 FCC limits), July 17, 2020
- A T &T Small Cells in Communities Richfield Minnesota, dated 2020
- Jerrold Bushberg "Introduction to Potential Health Considerations of 5G Networks" at the Beverly Hills California Health and Safety Commission Meeting (See Agenda, Watch video, See full transcript) February 24, 2020
- Verizon to City of Everett MA, February 13, 2020
- Eric Swanson Testimony to PA State Legislatures Re: Health Effects of 5G Telecommunication Infrastructure, June 12, 2019
- CTIA Wireless Industry Letter to the Senate and House Chair of the Massachusetts Joint Committee on Public Health opposing wireless bills, June 7, 2019

- CTIA Testimony to Hawaii Legislature (includes CTIA website Info plus Christopher Davis and Eric Swanson Testimony) March 21, 2019
- CTIA Testimony to Montana Legislature, February 7, 2019
- CTIA Testimony to Connecticut General Assembly January 28, 2019
- Jerrold Bushberg Testimony to San Anselmo, CA on cell tower, June 8, 2017
- Testimony of Christopher Davis for CTIA
- Testimony of Christopher Davis for CTIA for Michigan
- Verizon Health and Safety Testimony
    - Verizon Testimony to Neptune Township New Jersey (includes CTIA Health and Safety Info and Testimony of Eric Swanson March 11, 2019
    - Verizon Testimony to Coeur d'Alene Idaho, March 4, 2020
    - Verizon https://improveyourwireless.com/northcarolina/
    - Verizon Presentation Town of Morristown, New Jersey March 2021 (Note te press then cited the FDA statement in their news report on the issue in an article in Morristown Green March 24, 2021)
    - Glendale California: 9/22/21Verizon testimony
    - City of Malibu; RE: Verizon Wireless Small Cell Sites (listed below) Located in Malibu CA, July 27, 2019
    - Verizon Improve Your Wireless Pacifica
    - Verizon Highlands Ranch Metro District
    - Verizon Wireless Letter to City of Salem Massachusetts 1/26/2021
- Smartlink LLC on behalf of AT and T, for City of Independence California, Staff Report May 27, 2020

News Stories Featuring FDA

MIT Technology Review "No, there's no evidence that cell phones give you cancer"
February 11, 2020
Inside Towers, "The FDA Says Cell Phones Don't Cause Cancer and Rat Study is Flawed"
February 13, 2020
ZDNET, "Do cell phones give you cancer? There's no evidence for it, says US's FDA"
February 11, 2020
How Stuff Works, "How Cell-phone Radiation Works"
Bloomberg, "FDA sees no evidence cell phones can cause cancer"
Pocketables, "FDA says there's scientific evidence cell phones are safe"
February 11, 2020
Wall Street Journal, "FCC Says 5G Doesn't Pose New Cellphone-Radiation Threats"
December 5, 2019

Recent News Stories on FCC Limits and Federal Assurances

Wall Street Journal, "Are Airpods Out: Why Cool Kids Are Wearing Wired Headphones"
November 13, 2021

13 News "Verify: Airpods do not produce EMF RF waves stronger than phone dangerous to heath"
November 9, 2021

News Stories on NTP Study Reports
CNN, "Federal health agencies disagree over link between cell phone radiation and cancer"
November 1, 2018
Scientific American New Studies Link Cell Phone Radiation with Cancer"
March 29, 2018
Reuters,"High levels of cellphone radiation linked to tumors in male rats: U.S. study"
February 2, 2018
New York Times, Cancer Risk From Cellphone Radiation Is Small, Studies Show"
February 2, 2018
Science, "New cellphone and health studies don't eliminate uncertainty"
February 3, 2018
Forbes, What Does Bombarding Rodents With Cell Phone Radiation Tell Us About Risks To Humans? November 4, 2018
Daily Mail, FDA insists cell phones ARE safe - despite new government study that found 'clear evidence' of link to heart and brain cancers in rats, November 2, 2018
Medscape "Cancer Fears Over Cell Phones, Again, but FDA Disagrees." November 2, 2018
The Verge, Cellphone radiation poses no real harm to humans, new research says, February 2, 2018
The Verge, 5G Everything You Need to Know, June 9, 2020

- FDA Denial of Petition Docket FDA 2013-P-1374 to Frederick S. Mayer, July 17, 2017
- Petition by Frederick S. Mayer to the FDA
- Supplemental Material in Mayer Petition to the FDA

Congress ignores concerns

U.S. Senator John Hickenlooper, January 3, 2024 on Connect Our Parks does not respond to health and environmental issues raised

The FCC accurately uses the FDA as proof of safety.

FCC to U.S. Senator Van Hollen	The FCC shares the concern that Federal regulations protect the health of the public with respect to exposure to RF emissions at all times and in all locations. The policy of the FCC with respect to RF emissions was developed to ensure that FCC-regulated transmitters do not expose the public to levels of RF energy that are considered by organizations expert on human health and safety to be potentially harmful. The U.S. Food and Drug Administration (FDA) maintains that the available scientific evidence does not support adverse health effects in humans due to exposures at or under the current FCC limits. All licensed transmitters, including 5G base st tion antennas, must confirm compliance with these FCC limits or prepare an Environmental Assessment on the basis of human exposure to RF energy.

Congress and State Officials Letters and Communications of False Safety Assurances to Constituents After They Raise Health Issues

Letter From U.S. Senator Bernie Sanders January 31, 2024	According to the National Institutes of Health (NIH), all cell phone radiation—including that emitted by 5G cell phones—falls in the "nonionizing" range of the radiofrequency spectrum. This means that the energy emitted by cell phones is too low to damage DNA or increase core body temperature. Moreover, numerous studies that investigated the relationship between cellphone radiation and health effects on the human body failed to show an association between the two. If you are concerned about your own exposure to these nonionizing radiofrequencies, the Food and Drug Administration's (FDA) guidance encourages limiting long calls on cell phones or using your cell phone hands-free when making calls.
U.S. Senator Peter Welch January 3, 2024	The Federal Communications Commission (FCC) has a robust process to assess and regulate new technologies, including 5G wireless devices. The FCC sets its guidelines and rules regarding safe radiofrequency (RF) exposure in accordance with other government agencies and research by the Institute of Electrical and Electronics Engineers (IEEE) and the National Council on Radiation Protection and Measurements (NCRP). Currently, no scientific evidence suggests a causal link between wireless device use and illness, but the FCC will continue to consider health risks as new technologies are developed.
Representative Doris Matsui December 20, 2023	I am committed to protecting public health and ensuring that new technologies are well-studied, well-regulated, and do not endanger the public.. "According to the World Health Organization, which extensively reports on analysis from around the world, there is no credible research to date that finds evidence of adverse health effects from exposure to 5G radiofrequency (RF) fields. The monitoring and investigation of RF exposure on public health is a

	collaborative effort between several federal agencies. Since 1996, the FCC has required all wireless communications devices sold in the United States to meet minimum guidelines for safe human exposure to RF energy. RF exposure standards are developed by subject matter experts such as the Institute of Electrical and Electronics Engineers (IEEE) and the National Council on Radiation Protection and Measurements (NCRP) and are used by federal, state and local governments to regulate the teleservice industry and protect public health. These regulators and experts have not found conclusive, significant or causal evidence to suggest that 5G is harmful to humans
U.S. Senator Angus King October 17, 2023	I also understand there are concerns about possible health risks related to the radio frequencies used in 5G technology. You may be relieved – as I was – to know that studies from reputable institutions – such as Cornell University and the World Health Organization – have concluded that exposure to the spectrum used by 5G does not pose significant risks to human health, especially compared to other frequencies that have been in wide use for years.
U.S Senator Schumer February 6, 2023 Also U.S. Senator Schumer July 22, 2022	“Rest assured that as additional studies on microwave radiation and RF exposure are published by scientists and reviewed by government agencies…” “As you may know, the Federal Communications Commission (FCC) is required by the National Environmental Policy Act (NEPA) of 1969 to evaluate the effect of emissions from FCC-regulated transmitters on the quality of the human environment.” . “Many other federal agencies, such as the EPA, FDA, NIOSH, OSHA have been actively involved in monitoring and investigating issues related to RF exposure.”
U.S Senator Schumer July 21, 2023	“Since 1996, the FCC has required that all wireless communications devices sold in the United States meet its minimum guidelines for safe human exposure to RF energy.” “Many other federal agencies, such as the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Institute for Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Administration (OSHA) have been actively involved in monitoring and investigating issues related to RF exposure.” “Rest assured that as additional studies on microwave radiation and RF exposure are published by scientists and reviewed by government agencies, I will closely monitor the issue. “

U.S. Senator Schumer May 11, 2023 Letter on electromagnetic sensitivity	I agree that as wireless technology is expanded across the country, Congress must monitor how this technology is implemented as the scientific evidence evolves. Rest assured that as additional studies on EMS are published by scientists and reviewed by government agencies, I will closely monitor the issue.
U.S. Senator Angus King, March 31, 2023	"I also understand there are concerns about possible health risks related to the radio frequencies used in 5G technology. You may be relieved – as I was – to know that studies from reputable institutions – such as Cornell University and the World Health Organization – have concluded that exposure to the spectrum used by 5G does not pose significant risks to human health, especially compared to other frequencies that have been in wide use for years. In fact, much of the speculation on 5G's danger has been propagated by RT, the Russian government's media arm in the United States, in an attempt to give Russia a competitive advantage in 5G technology development. If you are interested, I encourage you to read a New York Times report that details Russia's efforts to spread misinformation about 5G's health risks via the following link: https://www.nytimes.com/2019/05/12/science/5g-phone-safety-health-russia.html. As you may be aware, regulatory authority over the deployment of 5G networks rests largely with state and local governments, but also with the Federal Communications Commission (FCC). While I am not able to intervene directly in local decisions, as 5G's rollout continues, I will remain apprised of the collaboration between the FCC, private enterprise, and state and local officials to ensure that consumers can be confident that this new technology is safe for use in all respects."
Rep. Scott Fitzgerald November 5, 2021	"All wireless devices sold in the United States go through a formal FCC approval process to ensure that they do not exceed certain exposure limits when operating at the device's highest possible power level." "In addition to the FCC, Federal health and safety agencies such as the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) have been actively involved in monitoring and investigating issues related to radio frequency (RF) exposure."
Rep. Alan Lowenthal October 18, 2021	"This technology will lead to faster data speeds and greater network capacity for phone and computer users. Some individuals have expressed concern about small cell technology, yet to date, no credible scientific evidence points to a public health risk from small cell signals." "I will continue to study the issue and make sure that these agencies use the best available science to guide their work."

Senator Kyrsten Sinema October 7, 2021	Arizona is leading the way in advancing 5G technology. As Arizona's senior senator, I supported S. 893 and S. 1260 because I understand the importance of Arizona's leadership in testing and implementing technological developments, “I understand that 5G deployment must promote transparency, do no harm, and protect fundamental privacy rights.”
Representative Trone October 27, 2021 And September 20, 2021	“Thank you for sharing your thoughts with me regarding the construction of 5G towers. I recognize that with new technologies often come new public safety risks. According to the NIH and the American Cancer Society, there is no strong evidence that exposure to 5G towers causes negative health effects. I believe that we should continue to research this new technology to ensure Americans are kept safe from any potential unknown risks.”
Representative Chrissy Houlahan October 8, 2021	“For our nation to remain on the cutting edge of innovation, we must also make strategic investments in 5G technology.” “I understand you wrote with concerns, and I appreciate you sharing your views. Please know that I am taking them into consideration as I try to make the best decisions I can for our community. We may not agree on this issue, but I hope you will continue to engage with me and my office because I value your continued input.”
Representative Brad Wenstrup September 16, 2021	**“As technological advancements continue we should be aware of potential health risks and develop protections so that we are not putting ourselves at risk for serious health conditions.”**
Senator Diane Feinstein, September 6, 2021	“I understand you are concerned that the deployment of 5G may expose some Americans to unhealthy levels of radio frequency. As you may know, the Federal Communications Commission (FCC) is in charge of setting the standards for radio frequency exposure to the public. The current FCC guidelines are based on recommended exposure criteria issued by the American National Standards Institute, among other organizations. Since 1996, it has been the FCC’s policy to cooperate with industry, expert agencies, and health and safety organizations to ensure that guidelines continue to be appropriate and scientifically valid.”
Senator Sherrod Brown, September, 26, 2019 U.S. Senator Sherrod Brown	2019 Letter “In November 2018, the US Department of Health and Human Services' National Toxicology Program (NTP), concluded a study on the effects of 2G and 3G cell phone radiation in rodents. The study found evidence that radio frequency radiation from the devices caused tumors in mice and rats. Although the experiment did not use 5G cellular radiation to determine its effects on test subjects, I remain deeply concerned about the results of the study.”

Letter to Constituent April 23, 2022	"5G wireless networks bring the promise of an increase in internet speed that will change the way Americans access information and entertainment content, the way local transportation and critical infrastructure systems work, and the way business transactions are completed. Ohio's cities will need robust 5G networks if they are to remain competitive places to do business, but not at the expense of the health of Ohioans." 2022 Letter In November 2018, the U.S. Department of Health and Human Services' National Toxicology Program (NTP) concluded a study on the effects of 2G and 3G cell phone radiation in rodents. The study found evidence that radiofrequency radiation from the devices caused tumors in mice and rats. This study did not evaluate 5G cell phone radiation; 5G phones are anticipated to use a different radiofrequency than 2G and 3G devices. For more information on cell phones and cancer risk, please visit the National Cancer Institute's (NCI) website here: https://www.cancer.gov/about-cancer/causes-prevention/risk/radiation/cell-phones-fact-sheet.
Representative Anna Eshoo September 20, 2019	"On September 9, 2019, Dr. Jeffrey Shuren and Dr. Edward Margerrison of the Food and Drug Administration (FDA) sent me an eight-page detailed review of the scientific evidence regarding the safety of radiofrequency radiation (RFR), including an explanation of methods the agency uses for analyzing scientific evidence on the topic. As the FDA officials noted to me, the agency concludes that the current RFR safety limits for cellphones are acceptable to protect public health. These conclusions hold for 5G technologies."
Representative Brad Wenstrup September 17, 2019	"Thank you for contacting me regarding EMF radiation and installation of 5G devices on personal property...You may be interested to know that according to the National Institutes of Health (NIH), current research points to a very weak association between EMFs and adverse health effects. You may find information on NIH's website, found here, helpful...I believe we must ensure telecommunications providers are given the regulatory certainty to deploy this technology in a safe way that does infringe upon an individual's constitutional rights."
U.S Senator Tammy Baldwin November 4, 2019	"It should be emphasized that the Federal Communications Commission (FCC) is not a health and safety organization, and so we have rely on the expertise of other organizations and agencies with respect to the biological research necessary to determine what levels are safe." "Our rules regulating these fields are based on recommendations from the US Environmental Protection Agency (EPA), the Food and Drug Administration, and other federal health and safety agencies, and are derived from exposure limits recommended by the Institute of Electrical and Electronics engineers Inc.

	(IEEE) and the National Council on Radiation Protection and Measurements (NCRP). Both IEEE and NCRP have extensive experience and knowledge in the area of RF biological effects and related issues and have spent a considerable amount of time evaluating published scientific studies, including the studies of the health status of expose persons, relevant to establishing safe levels for human exposure to RF energy." **"On its Web page the FDA maintains that the available scientific evidence to date does not support adverse health effects in humans due to exposures at or under the current limits, and that it is committed to protecting public health and continues its review of the many sources of scientific literature on this topic."**
U.S. Senator Markey Letter to Constituent on 5G September 18, 2018	"With technology expanding into nearly every facet of our lives, we need to ensure all Americans- whether urban or rural, rich or poor-remain connected and competitive in this global economy. We can and must balance this need for connectivity with important health considerations."
Senator Tammy Baldwin September 13, 2017	"I understand your concerns about the health impacts of wireless technologies, including proximity to a cellular tower. According to studies conducted by the Centers for Disease Control and Prevention (CDC), in coordination with the Food and Drug Administration (FDA) and FCC, radio frequency emissions exposure from cellular towers is thousands of times below safety limits and significantly lower than that from emissions by television antennas and radio broadcast towers. However, I will closely monitor these and other agencies to ensure that we continue to study the health impacts of current and emerging technologies."
U.S. Senator Markey July 26, 2017	"Thank you for contacting me about the Making Opportunities for Broadband Investment and Limiting Excessive and Needless Obstacles to Wireless (MOBILE NOW) Act (S. 19). It was good to hear from you on this important issue. The MOBILE NOW Act includes provisions that would accelerate the development of next-generation 5G wireless broadband by ensuring more spectrum is made available for commercial use. The legislation was referred to the Committee on Commerce, Science, and Transportation, and is now pending action by the full Senate. I plan to closely monitor this legislation moving forward."
Pennsylvania State Representative Mark M. Gillen	"The FCC also consulted federal health and safety organizations such as the Food and Drug Administration (FDA), the Environmental Protection Agency, the Occupational Safety and Health Administration, and the National Institute for Occupational Safety and Health to develop "consensus" regulations. Together, these bodies have assessed

	thousands of scientific studies concerning possible health effects of nonionizing radiation. …Dr. Swanson testified that the technology used in small cells is more than 30,000 times below the ionizing threshold and 500 times lower than the FCC limit. His statements are supported by the FDA, the National Cancer Institute, the American Cancer Institute and the World Health Organization."

Best examples

- Representative Anna Eshoo September 20, 2019
- U.S Senator Tammy Baldwin November 4, 2019

"On its Web page the FDA maintains that the available scientific evidence to date does not support adverse health effects in humans due to exposures at or under the current limits, and that it is committed to protecting public health and continues its review of the many sources of scientific literature on this topic."

Officials Support 5G Claiming it Will Benefit Consumers

Senator Alex Padilla Letter to Constituent on 5G December 2022

"Thank you for writing to share your concerns regarding 5G technology. I appreciate hearing from you. I believe that strengthening U.S. leadership in 5G technologies will stimulate American innovation, create new economic opportunities for businesses, and ultimately benefit consumers…
While we may disagree on this issue, I hope you will continue to contact me regarding issues of importance to you."

State Entities and Officials

Florida Department of Environmental Protection to Florida Resident, January 22, 2013

- "In addition, the U.S. Food and Drug Administration (FDA), in collaboration with the FCC, regulates wireless technology devices such as wireless computer networks and cellular phones. FDA monitors the health effects of wireless phones and has authority to take action if wireless phones are shown to emit RF at a level that is hazardous to the user. FDA's website is http://www.fda.gov/"

Pennsylvania State Representative Mark M. Gillen wrote a letter to a concerned constituent

"The FCC also consulted federal health and safety organizations such as the Food and Drug Administration (FDA), the Environmental Protection Agency, the Occupational Safety and Health Administration, and the National Institute for Occupational Safety and Health to develop "consensus" regulations. Together, these bodies have assessed thousands of scientific studies concerning possible health effects of nonionizing radiation.

> …Dr. Swanson testified that the technology used in small cells is more than 30,000 times below the ionizing threshold and 500 times lower than the FCC limit. His statements are supported by the FDA, the National Cancer Institute, the American Cancer Institute and the World Health Organization."

Local Officials, Government Agencies and Entities

Montgomery County MD Councilman Hans Riemer newsletter July 28, 2021

"What do leading public health authorities say about cell phones and 5G?

> Safety comes first. Fortunately, the science on wireless waves is compelling. The leading national and international scientific institutes continue to find that cell phones are not linked to health problems. The FDA, which we are proud to have located here, reviews the existing studies and puts them all into a balance. The FDA clearly says, the "weight of scientific evidence has not linked cell phones with any health problems."
>
> In addition to the FDA, here is what leading public health authorities have to say on this topic:"

- Montgomery County MD Councilman Hans Riemer Tweet July 14, 2021

Montgomery County School District
District Letter on FCC and FDA Safety Assurances, March 12, 2014 " According to the FDA and the World Health Organization, the weight of scientific evidence has not effectively linked exposure to RF energy from mobile devices with any known health problems."
Montgomery County School District RF Review- For example, when parents raised the health issue in Montgomery County Schools, the school district released a web page where the FDA was listed as performing a 2013 research review which concluded that:

> *"Studies on biological changes were not replicated. No evidence for health problems in adults, children and teenagers."*

Town of Tucson Arizona -FAQs on Small Cells References FDA

"As the City of Tucson does not and cannot, under state and federal law, regulate small cell wireless technology based on health concerns, the following Federal and World Health Organization resources are provided to answer questions:

- https://www.fcc.gov/engineering-technology/electromagnetic-compatibility-division/radio-frequency-safety/faq/rf-safety
- https://www.fcc.gov/consumers/guides/wireless-devices-and-health-concerns
- https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/cell-phones”

City of Sacramento **5G FAQS: WHO DETERMINES SAFETY STANDARDS FOR 5G?**

“WHO DETERMINES SAFETY STANDARDS FOR 5G?

The FCC, in consultation with numerous other federal agencies, including the Environmental Protection Agency, the Food and Drug Administration and the Occupational Safety and Health Administration, determines safety standards for wireless networks.”

https://ehtrust.org/wp-content/uploads/Representative-Rashida-Tlaib-5G-Health-Effects-Letter-.pdf